

# **GRADUATE PROGRAM HANDBOOK**

**Department of Food Science**

**The Pennsylvania State University**

**Volume III**

**Department and University Policies**

**Academic Year 2014-2015**

PENNSSTATE



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## INTRODUCTION

Volume III of the Graduate Handbook Provides a ready access to department and University policies applicable to most graduate students and research laboratories.

The University's full library of policies can be found the General Universal Reference Utility (GURU) accessed via <http://guru.psu.edu/policies/>

The department's policies and forms can be found on the department's intranet site that can be accessed on through the department's website <http://foodscience.psu.edu/> and using the '**Faculty and Staff Resources**' navigation bar on the lower lefthand side of the page or directly via <https://agsci.psu.edu/intranet/foodscience>

In addition to policies and forms, information such as faculty, staff, and student directories, telephone and copier goperating guidelines, and seminar schedules may be found on the department's intranet.

## **PROCEDURES AND REGULATIONS — FOOD SCIENCE DEPARTMENT RESEARCH LABORATORIES**

The Department operates its research laboratories in a very open manner; that is, with appropriate permission, people are relatively free to use equipment and space in various labs as needed for their research. This is possible, however, only with the courtesy, cooperation and respect of everyone working together. **Please make ask the appropriate faculty or staff before using, adding or removing equipment and supplies from the laboratories.**

The different laboratories and the person-in-charge are:

Food Science Building

<u>Room Number</u>	<u>Faculty</u>	<u>Room Number</u>	<u>Faculty</u>
103	Ford/Palchak	319	Hayes/Gardner
132 chemistry/249 microbiology teaching labs	Lumley-Sapanski	320	Vanamala
134 (wet)/135 (dry) pilot plants	Lumley-Sapanski	408	Roberts
225	Hayes	409	LaBorde
228, 243, 244     Sensory Lab Center	Hayes	410	Beelman
307	Anantheswaran	415	Cutter, Doores
308/309	Ziegler	418	Knabel
315	Coupland	419	Cutter
316	Elias	420	Doores
317	Harte	421	Dudley
318	Lambert		

Be sure to sign out when removing equipment from another laboratory. Write down the piece of equipment borrowed and when it was borrowed. Be sure to return equipment as soon as you are finished with it and write down the date the equipment was returned.

### **HAZARDOUS AGENTS -- USE AND DISPOSAL**

Although the Facilities Coordinator, Robert Lumley-Sapanski, is ultimately responsible for coordinating hazardous waste disposal in the Food Science department, each graduate student is responsible for the proper disposal of his/her waste. Any questions regarding proper disposal should be addressed to the Facilities Coordinator. See also Appendix A 5.

The University has policies governing the use and disposal of any material which may be hazardous to health or the environment. These policies conform to regulations promulgated by the Pennsylvania Department of Environmental Resources, the U.S. Environmental Protection Agency, the U.S. Department of Health Education and Welfare, and other pertinent government agencies.

#### **Food Science Department Flammable Solvent and Hazardous Waste Policy -**

In addition to generally accepted chemistry laboratory safety procedures, the following precautions must also be noted:

1. Flammable solvents should not be stored in refrigerators or cold rooms that are not explosion proof.
2. When working with flammable solvents, always use fume safety hoods. Under no circumstances should flammable solvent fumes be detectable in the hallways of the Food Science Laboratory or in the Meats Laboratory.
3. All flammable solvents should be stored in approved safety cans or in safety storage cabinets. There are cabinets in the Food Science Building to store small amounts of solvents in. Appropriate arrangements can also be made for the storage of bulk solvents.
4. Disposal of waste solvents -- Solvents must not be poured down the drain. Containers in this cabinet are labeled for solvents commonly used, for example "Waste Ethyl Ether." **Everyone** is responsible for transferring their waste solvents into these containers. If there is not a container available for the solvent or mixture you are using, it is your responsibility to make arrangements for a properly labeled

container. Periodically, you must also make arrangements with the university's Office of Environmental Health and Safety (EHS) to dispose of waste solvents. If you have questions about this procedure, you can contact the Facilities Coordinator for assistance.

**Flammable Solvents and Hazardous Waste** - All graduate students are responsible for the inventory and disposal of their solvent waste. The primary responsibility of this student will be to assist with chemical waste generated in the teaching laboratory because each research laboratory is independently responsible for its own waste disposal. Pick up of all chemical waste must be scheduled electronically at the EHS website, [www.ehs.psu.edu](http://www.ehs.psu.edu).

**Radioactive Materials** - These materials are handled by the University Health Physics Department, 228 Academic Projects Building. All radioisotope users are required by University and federal regulations to receive basic instruction in radiation safety. The Health Physics Office at Penn State regularly offers a 4 hour radiation orientation/safety class. An exam is given at the end of this class. Any student that will be working in a laboratory containing radioisotopes — **whether or not these isotopes will be handled by that student** — MUST take this course. When class dates are announced, they will be posted on the door to the first floor copy room.

**Biohazard Materials** - This class of materials includes infectious agents and chemical carcinogens. Specific information can be found in each laboratory's "Laboratory and Research Safety Plan. A bound booklet published by the University Biohazards Committee is available to describe the use and disposal of Biohazards. The Department of University Safety, Safety Services has copies for distribution of the "Biohazards Control and Procedures manual" of Penn State. All biohazard waste must be autoclaved prior to collection by the Environmental Health and Safety Office. All used petri plates and tissue culture flasks must be double-bagged within Autoclave Bags for Biohazard Materials. Following autoclaving, each bag must be placed into the large, white "Biohazard" waste cans located near every autoclave in Borland. Any plastic culture ware which has not been used but is to be disposed of, may be deposited in the normal trash containers. All plastic pipettes, Pasteur pipettes, and syringes with needles which have been in contact with any viable organisms must be deposited in autoclavable sharps containers. These containers must be marked with autoclave tape, autoclaved and placed in or next to the large, white Biohazard waste cans and collected by Environmental Health and Safety for disposal. Any sharp items not in contact with any viable organisms may be disposed of in the waste receptacles intended for broken glass disposal, which should be located throughout the labs.

All reusable glassware which has been in contact with viable organisms must be autoclaved within leakproof autoclavable containers before it is washed and reused. This includes all glass pipettes, flasks, beakers, plates, syringes, etc.

**Hazardous Materials** - This University policy covers any hazardous materials not covered by other University Policies. This policy is termed "The Hazardous Waste Disposal Policy".

**Other Research Procedures:**

- Human Participants in Research - University policy concerning this issue is stated in Appendix A-5.
- Care and Use of Vertebrate Animals - University policy on this subject is covered in Appendix A-6.
- General Standards of Professional Ethics - See Appendix A-1.
- Handling Inquiries/Investigations into Questions of Ethics in Research and In Other Scholarly Activities - See Appendix A-3.
- Co-authorship of Scholarly Reports, Papers and Publications - See Appendix A-4.

**EMERGENCY CONTACTS:**

Please contact one of the following for facility, equipment or other emergencies:

- Bob Lumley-Sapanski
- Tom Dimick
- Kim Ripka

## GRADUATE STUDENT RESOURCES

**University Office of Global Programs** provides answers to questions and needs that are unique to international students. The office is located at 410 Boucke Building. <http://www.international.psu.edu/>

**Graduate Student Association (GSA)** is the representative body for all graduate students. The GSA addresses issues of concern to graduate students and elects members to sit on shared-governance bodies of the University. The GSA also organizes social events for graduate students. <http://www.clubs.psu.edu/up/gsa/>

**The Office of Student Aid** is a good place to begin the search for financial assistance. <http://www.psu.edu/studentaid/>

**The Office for Disability Services** provides information and assistance to students with disabilities. <http://www.equity.psu.edu/ods/>

**The Writing Center** is sponsored by the Graduate School and provides assistance to graduate students who wish to enhance their writing skills. Graduate students are invited to schedule appointments for one-on-one discussions of their writing projects. <http://www.psu.edu/dept/cew/GWC.shtml>

**Penn State Escort Service** is operated under the auspices of Police Services and will provide an escort for students walking on campus after dark. The escort service may be reached at 5-WALK (865-9255). <http://www.psu.edu/dept/police/escortservice.html>

**Off-Campus Housing** opportunities are listed in 213 HUB-Robeson Center, 865-2346. <http://www.sa.psu.edu/ocl/>

**Office of Judicial Affairs** is responsible for dealing with violations of the Code of Conduct including sexual assault, harassing, stalking, and physical assault. The phone number is 863-0342. <http://www.sa.psu.edu/ja/>

**The Code of Conduct** is available at <http://www.sa.psu.edu/ja/conduct.shtml>

**The Affirmative Action Office** is committed to ensuring the University maintains an environment free of harassment and discrimination. <http://www.psu.edu/dept/aaoffice/>

**HUB-Robeson Center** is the site for multiple student services including restaurants, a copy center, a bank (Penn State Federal Credit Union), STA Travel, a convenience store, the Penn State Bookstore, the Center for Arts and Crafts, Art Galleries, and the main information desk for the University. <http://www.sa.psu.edu/usa/hub/>

**Counseling and Psychological Services (CAPS)** can help students resolve personal concerns that may interfere with their academic progress, social development, and satisfaction at Penn State. Some of the more common concerns include difficulty with friends, roommates, or family members; depression and anxiety; sexual identity; lack of motivation or difficulty relaxing, concentrating or studying; eating disorders; sexual assault and sexual abuse recovery; and uncertainties about personal values and beliefs. <http://www.sa.psu.edu/caps/>

**Career Services**, located in the MBNA Career Services Building, is fully equipped to assist graduate students in the preparation of resumes and curriculum vitae and in developing effective interviewing skills. Career Services hosts a career fair that is open to graduate as well as undergraduate students. <http://www.sa.psu.edu/career/>

**Research Protections** is the office that oversees all research on human participants, animals, radioisotopes and biohazardous materials. You must have permission from this office prior to conducting research involving any of these subjects. Permission can not be obtained after the work has begun. <http://www.research.psu.edu/orp/>

**Pasquerilla Spiritual Center** is home to more than fifty spiritual organizations. The center is non-denominational and provides students with opportunities to explore ethical and spiritual issues.

<http://www.sa.psu.edu/insights/jan04/spiritual.shtml>

### **Problem resolution**

Graduate students occasionally have difficulties with their advisors, their programs or an academic matter associated with their programs. The first step in problem resolution is always to talk with your advisor and then with the program chair or department head and then the associate dean of your college. If satisfactory resolution remains elusive, the associate dean of the Graduate School is available to provide guidance and maintain neutrality. Issues discussed during meetings with the assistant dean will remain confidential if requested by the student. Appointments may be made by calling 865-2516.

### **Academic Integrity**

The University does not tolerate violations of academic integrity, which include but are not limited to: plagiarism, cheating, falsification of information, misrepresentation or deception. The complete policy is available at: <http://www.psu.edu/dept/ufs/policies/47-00.html#49-20>

### **Plagiarism**

Plagiarism is often a confusing concept. At Penn State, plagiarism means taking someone's words and presenting them as your own. Cutting and pasting from a web site is considered plagiarism. Copying verbatim from any source without using quotation marks and the full reference is plagiarism. Plagiarism is a serious violation of academic integrity regardless of whether it is a homework exercise, an exam, a thesis, or a manuscript for publication.

**University policies** may be viewed on line. Important policies include:

Sexual Harassment (AD41)

Professional Ethics (AD47)

Parking Rules (BS04)

Intellectual Property (RA11)

<http://www.guru.psu.edu/policies/>

**Graduate Student Policies** are available on line

These include:

Grade mediation (G-10)

Resolution of problems (Appendix II)

Termination of program (Appendix III)

Termination of assistantship (Appendix IV)

Residency requirements (Appendix V)

<http://www.gradsch.psu.edu/index.cfm/policies/>



## **ELECTRONIC SUBMISSION OF THESES AND DISSERTATIONS (ETD)**

Electronic submission of the final dissertation (eTD) became a requirement for all doctoral candidates at Penn State starting in fall semester 2006. Master's candidates now have the choice of submitting the final thesis either in the traditional paper format or as an electronic document. (It cannot be submitted as both.) Formatting requirements are essentially the same for a paper copy and an eTD, but the submission process itself is somewhat different. For additional information on the mechanics of eTD preparation, visit the eTD Web site <http://www.etsd.psu.edu/>

## **REFERENCE PUBLICATIONS**

"Graduate Degree Programs." Dean of the Graduate School, 114 Kern Building, University Park, PA 16802. <http://www.psu.edu/bulletins/whitebook/>

"Policies and Procedures." Office of the Vice-president for Student Affairs, 101 Boucke Building, University Park, PA 16802. <http://www.psu.edu/oue/aappm>

"A Guide to Graduate Life." Graduate Student Association, 111B Kern Building, University Park, PA 16802. <http://www.clubs.psu.edu/up/gsa/NGGLMAIN.html>

"Thesis Guide." Graduate Thesis Office, 115 Kern Building, University Park, PA 16802. <http://www.gradschool.psu.edu/index.cfm/current-students/thesis-and-dissertation-information/>

## APPENDIX A 1 Administrative Policy AD47

### GENERAL STANDARDS OF PROFESSIONAL ETHICS

<http://guru.psu.edu/policies/AD47.html>

#### Contents:

- [Purpose](#)
  - [Statements](#)
  - [Cross References](#)
- 

#### PURPOSE:

To set forth statements of general standards of professional ethics to serve as a reminder of the variety of obligations assumed by all members of the academic community

#### STATEMENTS:

I. Professors, guided by a deep conviction of the worth and dignity of the advancement of knowledge, recognize the special responsibilities placed upon them. Their primary responsibility to their respective subjects is to seek and to state the truth as they see it. To this end, they devote their energies to developing and improving their scholarly competence. They accept the obligation to exercise critical self-discipline and judgment in using, extending, and transmitting knowledge. They practice intellectual honesty. Although they may follow subsidiary interests, these interests must never seriously hamper or compromise their freedom of inquiry.

II. As teachers, professors encourage the free pursuit of learning in their students. They hold before their students the best scholarly standards of their respective disciplines. They demonstrate respect for the student as an individual, and adhere to their proper role as intellectual guides and counselors. They make every reasonable effort to foster honest academic conduct and to assure that their evaluations of students reflect the students' true merit. They respect the confidential nature of the relationship between professor and student. They avoid any exploitation of students for private advantage and acknowledge significant assistance from them. They protect their students' academic freedom.

III. As researchers/scholars, professors recognize that their goal is to discover, develop, and communicate new understanding. This goal is rarely achieved without making use of knowledge gained from others. Researchers must always exercise gracious and appropriate recognition of published work in the literature, conversations with colleagues, and the efforts of students who work under the researchers' guidance. They must be scrupulous in presentation of their own data; it must be verifiable as a result of the highest standards in data gathering techniques. They must be extremely careful in the use of data reported by others, especially if used in the formation of broad comparative or contradictory hypotheses, since they may not know of any compromising circumstances in such data gathering. They must be comprehensive in consideration of work with human subjects; they must have thoroughly researched all procedures, must have informed individuals involved of all aspects of their cooperation, and must report all responses accurately, both positive and negative results. As open-minded researchers, when evaluating the work of others, they must recognize the responsibility to allow publication of theories or experiments that may contradict their own findings, as only by free inquiry and dissemination of all facts will the fruits of the labor of the whole community be allowed to mature.

IV. As colleagues, professors have obligations that derive from common membership in the community of scholars. They respect and defend the free inquiry of their associates. In the exchange of criticism and ideas they show due respect for the opinions of others. They acknowledge their academic debts and strive to be objective in their professional judgment of colleagues. They accept their share of faculty responsibilities for the governance of their institution.

V. As members of their institution, professors seek above all to be effective teachers and scholars. Although they observe the stated regulations of the institution, provided the regulations do not contravene academic freedom, they maintain their rights to criticize and seek revision. They determine the amount and character of the work they do outside their institution with due regard to their paramount responsibilities within it. When considering the interruption or termination of their service, they recognize the effect of this decision upon the programs of the institution and give due notice of their intentions.

VI. As members of the community, professors have the rights and obligations of all citizens. They measure the urgency of these obligations in the light of their responsibilities to their respective subjects, to their students, to their profession, and to their institution. When they speak or act as private persons they avoid creating the impression that they speak or act for their respective colleges or the University. As citizens engaged in a profession that depends upon freedom for its health and integrity, professors have an articular obligation to promote conditions of free inquiry and to further public understanding of academic freedom.

All tangible assets (including equipment, software, audio-visual material, theatrical costumes, etc.) owned, leased or operated by the University are to be used in the conduct of University programs and activities at University owned or leased locations.

>University departments may offer services only to other University departments and only for University-related work. Permitted work includes, instructional work for credit and non-credit courses, conferences, workshops, institutes, training programs, etc.; support for faculty research, publications, presentations, and outreach activities; services for recognized student organizations; and services for other organized student extramural activities.

University tangible assets and services may not be used for personal gain, by employees for purposes outside the scope of their employment (see also Policy [HR35](#)), or by students beyond their instructional requirements.

#### **CROSS REFERENCES:**

Additional Policies to refer to would include:

[RA10](#) - Handling Inquiries/Investigations into Questions of Ethics in Research and in Other Scholarly Activities,

[RA13](#) - Coauthorship of Scholarly Reports, Papers and Publications,

[HR35](#) - Public Service by Members of the Faculty and Staff,

>[HR91](#) - Conflict of Interest, and

>[RA14](#) - Use of Human Subjects in Research.

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Effective Date: May 10, 1996  
 Date Approved: June 10, 1996  
 Date Published: June 24, 1996 (Revision History added June 14, 2006)

#### **Most Recent Changes :**

- June 14, 2006 - Revision History added.

#### **Revision History (and effective dates):**

- May 10, 1996 - Former policy had been HR95 (previously PS95). Relocated to Administrative Policy section.
- March 24, 1989 - Title changes, plus addition of "Cross Reference" section.
- October 20, 1986 - New Policy.

## APPENDIX A 2 Payroll Policy PR06

### GRADUATE ASSISTANTS

<https://guru.psu.edu/policies/psu/PR06.html>

#### Contents:

- [Purpose](#)
- [Types and Salary Ranges](#)
- [Eligibility](#)
- [Offer of Appointment](#)
- [Responsibilities](#)
- [Length of Appointments](#)
- [Health Insurance Benefit](#)
- [Forms to be Completed By and For Graduate Assistants](#)
- [Submission of Forms for the Appointment of Graduate Assistants](#)
- [Submission of Forms for the Reappointment of Graduate Assistants](#)
- [Credits That May be Scheduled](#)
- [Evaluation and Performance](#)
- [Payment of Stipends](#)
- [Rates Charged to Funding Sources](#)
- [Changes](#)
- [Termination](#)

#### PURPOSE:

To state the Graduate Assistant Policy of the University.

#### TYPES AND SALARY RANGES:

Graduate assistantships are of three types: quarter-time, half-time, and three-quarter-time. The expected duration of assigned tasks is the same for all graduate assistants within the same type. Thus, for all quarter-time graduate assistants, irrespective of stipend, 10 hours of regular work per week are expected; for all half-time assistants, 20 hours; and for all three-quarter-time assistants, 30 hours. A semester normally consists of 18 full weeks, and extended summer session 12 weeks. Appointments are to be made at one of several grades in consideration of experience and qualifications of the individual. Refer to the [Table of Stipends for Graduate Assistants](#) and the [Penn State Graduate Degree Programs Bulletin](#) for further information.

Within any department or other administrative unit of the University, there shall be the same pay for the same work for graduate assistants regardless of the field of study in which the student is enrolled. This policy shall not preclude a scale of stipends based on merit, seniority or degree candidacy.

#### ELIGIBILITY:

A candidate for graduate assistantship must be eligible for admission to the Graduate School.

#### OFFER OF APPOINTMENT:

Every Graduate Assistant shall be offered his or her appointment each year in writing, using a standard form, the [Terms of Offer of a Graduate Assistantship](#), together with an individual letter of transmittal. The letter will indicate any extensive duties other than professional and preprofessional they will be called upon to perform.

**RESPONSIBILITIES:**

A graduate assistant may assist in classroom or laboratory instruction, in research or in other work. The tasks assigned to a graduate assistant often are identical in nature to those required for the advanced degree sought. If the duties are identical in nature to those required for the advanced degree sought, it must be noted in the Terms of Offer of a Graduate Assistantship, the individual letter of transmittal and on the appropriate IBIS appointment, reappointment or change form. Additional compensation is paid to a graduate assistant by the University for additional hours of work only with special, advance approval of the administrative head of the academic unit in which the assistantship is held, and of the chair of the student's graduate academic program, and provided that such compensation is not for additional hours of work on the assigned assistantship duties.

**LENGTH OF APPOINTMENTS:**

The appointment may be for the summer session or one or two semesters and must terminate on or before the end of the spring semester in any fiscal year. When an appointment will terminate before the end of the spring semester, the appointee should be informed of this when offered the assistantship.

**HEALTH INSURANCE BENEFIT:**

International Graduate Assistants are required to have health insurance coverage for themselves and their dependents in the United States. For domestic Graduate Assistants, health insurance is optional. The University provides a health insurance benefit as part of the assistantship contract. The University will pay a percentage of the annual premium for the Penn State Student Health Insurance Plan. The remaining percentage will be automatically deducted from the student's assistantship stipend. The University will not supplement, nor will a payroll deduction be made, for insurance policies other than the Penn State Student Insurance Plan.

International Graduate Assistants who have adequate alternate medical coverage and who do not wish to be enrolled in the Penn State Student Health Insurance Plan must submit a waiver application. In order to be granted a waiver, alternate plans must meet certain standards as established by the University Student Insurance Committee. This Committee will approve or disapprove the waiver application.

International Graduate Assistants who do not apply for a waiver will be automatically enrolled in the Penn State Student Insurance Plan.

(NOTE: Applications for a waiver demonstrating adequate alternate insurance must be submitted on a yearly basis each fall.)

Domestic Graduate Assistants will automatically enrolled in the Penn State Student Insurance Plan. Domestic Graduate Assistants who do not wish to be enrolled in the Penn State Student Insurance Plan must decline the insurance. Dependent health insurance coverage for domestic Graduate Assistants must be submitted on a yearly basis each fall.

For further information, contact the Student Insurance Office, 865-7467.

**FORMS TO BE COMPLETED BY AND FOR GRADUATE ASSISTANTS:**

A graduate assistant is appointed by completing an "NAPP/GFSA" in IBIS. Each appointment is approved, based upon the budget administrator's recommendation and certification of eligibility by the Dean of the Graduate School.

According to Policy [HR30](#), the budget executive is responsible for providing proof that there are no subversive persons employed in his/her area of responsibility.

In accepting an appointment as a graduate assistant, the recipient is required to complete the following forms:

1. [Employee's Withholding Allowance Certificate - Form W-4](#). Also, see Policy [PR13](#).
2. [Employment Eligibility Verification \(INS Form I-9\)](#).
3. [University Intellectual Property Agreements](#).
4. [Salary Deposit Request](#).

**SUBMISSION OF FORMS FOR THE APPOINTMENT OF GRADUATE ASSISTANTS:**

The Employee's Withholding Allowance Certificate (W-4) and Salary Deposit Requests are attached and submitted together to the Financial Officer. The forms are required in the Payroll Office **one month before** the first pay date each semester/session. The "GFSA" is approved and processed electronically.

Appointments are to be submitted in accordance with stipends authorized in the Table of Stipends for Graduate Assistants.

**SUBMISSION OF FORMS FOR THE REAPPOINTMENT OF GRADUATE ASSISTANTS:**

The "GRAD" is submitted with the block "Reappointment" marked. It is not required that a new Employee's Withholding Allowance Certificate (W-4) be completed if the graduate assistant's status (i.e., number of withholding exemptions, local earned income tax, address and/or name) is unchanged, providing that the graduate assistant's original appointment has not been terminated for more than a year.

**CREDITS THAT MAY BE SCHEDULED:**

The privileges of graduate study are the same for all graduate assistants within the same type. The table that follows shows the number of credits that normally may be scheduled for **each** semester or session.

	Fall/Spring	Summer
Graduate Assistant - Quarter-Time	9-14	5-7
Graduate Assistant - Half-Time	9-12	4-6
Graduate Assistant - Three-Quarter-Time	6-8	3-5

The credits specified are the number which the appointee is ordinarily expected to carry. With approval of the person to whom the student is responsible for his or her assignment, the credit load of a graduate assistant may be adjusted to take into account unusual departmental service loads in particular semester/sessions, provided:

- The credit load and the service load are properly balanced in each semester and the total credit load over a period of time conforms with the specified limits.
- The total number of credits scheduled during the interval of appointment is consistent with the type of appointment.
- The student is assigned no more than the normal work load during the first semester/session as a graduate student at the University, thus permitting him or her to be primarily a student during this period.

**EVALUATION AND PERFORMANCE:**

Each graduate assistant shall be supervised and assisted in assigned tasks until they gain experience and skill enabling them to take responsibility. Each graduate assistant shall have his or her work evaluated at least once each year, and the supervisor shall discuss with them how well they are considered to have performed.

**PAYMENT OF STIPENDS:**

All graduate assistant appointees are paid monthly. Direct salary deposits shall be mandatory and a condition of hire.

See the Schedule of Graduate Assistant Pay Dates, for pay dates and the portion of the stipend paid each month of the appointment.

Graduate assistants who miss the first regular monthly payroll may request a salary advance (of up to 70% of gross) through the Financial Officer. The Financial Officer will process an IBIS Special Request for Check for the advance. The subsequent payment will deduct the amount of advance.

Payments made in June for Summer Session are pre-payments against the following year's budget.

**RATES CHARGED TO FUNDING SOURCES:**

Graduate Assistant tuition will be charged to sponsored agreements at an average in-state rate.

Flat rate dissertation fees will be charged to a sponsored agreements for assistantships.

Tuition coverage through the Tuition Assistance Program is not available during any period for which the student is appointed on an assistantship.

**CHANGES:**

All changes to the appointment are accomplished by submitting an IBIS "GRAD."

**TERMINATION:**

All graduate assistant appointments are terminated automatically upon expiration without submitting termination forms; however, early terminations must be made by submitting an IBIS "TRMN/GFST."

The amount of final pay for an early termination is to be determined by subtracting the amount of stipend paid to the graduate assistant from the number of weeks of service rendered to the date of termination. If additional days are involved, the daily rate of 1/7th of the weekly rate applies.

Effective Date: March 24, 2005  
 Date Approved: March 11, 2005  
 Date Published: March 23, 2005

**Most Recent Changes:**

- March 24, 2005 -
  - In RESPONSIBILITIES section, added verbiage for proper completion when the tasks assigned to a graduate assistant are identical in nature to those required for the advanced degree sought.
  - In the HEALTH INSURANCE BENEFIT section, added verbiage that distinguished benefits of international Graduate Assistants and domestic Graduate Assistants.
  - Changed fall/spring credits for half-time Graduate Assistants from 8-11 to 9-12.
  - Editorial changes made throughout the policy, where applicable, to remove references to the General Forms Usage Guide.

**Revision History (and effective dates):**

- March 6, 2003 -
  - Provisions moved from Policy BT03 to this policy:
  - Payments made in June for Summer Session are pre-payments against the following year's budget.
  - Appointments are to be submitted in accordance with stipends authorized in the Table of Stipends (Appendix 5 of the General Forms Usage Guide).
  - Credits that may be scheduled by half-time graduate assistants increased from 8-11 to 9-12.

## APPENDIX A 3 Research Administration Policy RA10

### HANDLING INQUIRIES/INVESTIGATIONS INTO QUESTIONS OF ETHICS IN RESEARCH AND IN OTHER SCHOLARLY ACTIVITIES

<http://quru.psu.edu/policies/RA10.html>

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#### PURPOSE:

To establish a means to handle inquiries and/or investigations into questions of ethics related to research and other scholarly activities.

#### PREAMBLE:

Public trust in the integrity and ethical behavior of scholars is essential if research and other scholarly activities are to play their proper role in the University and in society. The maintenance of high ethical standards is a central and critical responsibility of faculty and administrators of academic institutions. Policy [AD47](#) sets forth statements of general standards of professional ethics within the academic community.

#### POLICY:

Violation of University policy shall be considered to be a serious breach of the trust placed in each member of the faculty and staff, as well as all students, and may result in the imposition of disciplinary sanctions, including, but not limited to, dismissal from employment or enrollment. Misconduct in research or other scholarly activities is prohibited and allegations of such misconduct in research shall be investigated thoroughly and resolved promptly.

Faculty and staff members and students have a personal responsibility for complying with this policy and for assisting their associates in continuing efforts to avoid any activity which may be considered in violation of University policy.

#### DEFINITION OF TERMS:

Research Misconduct:

- (1) fabrication, falsification, plagiarism or other practices that seriously deviate from accepted practices within the academic community for proposing, conducting, or reporting research or other scholarly activities;
- (2) callous disregard for requirements that ensure the protection of researchers, human participants, or the public; or for ensuring the welfare of laboratory animals;
- (3) failure to disclose significant financial and business interest as defined by Penn State Policy [RA20](#), Individual Conflict of Interest;
- (4) failure to comply with other applicable legal requirements governing research or other scholarly activities.

Research misconduct does not include disputes regarding honest error or honest differences in interpretations or judgments of data, and is not intended to resolve bona fide scientific disagreement or debate.



Allegation is defined as any oral or written statement of possible research misconduct made to an institutional official.

Inquiry is defined as information-gathering and preliminary fact-finding to determine whether an allegation or apparent instance of research misconduct warrants an investigation.

Investigation is defined as a formal examination and evaluation of relevant facts to determine whether research misconduct has taken place or, if research misconduct has already been confirmed, to assess its extent and consequences and determine appropriate action.

Budget Executive - Those individuals who are responsible to the President, Executive Vice President and Provost, or a Vice President for a section of the budget. These individuals are normally the President's administrative staff, academic Deans, and Chancellors. The budget executive approves transactions at the upper dollar levels and specified categories, affirming the programmatic need for the action and that the action is appropriate within University Policies and Guidelines.

Budget Administrator - Those individuals designated by the Budget Executive as being responsible for operating and controlling specific budget areas within the Budget Executive's administrative area. These individuals approve documents in their own name within the limits of the authorization policy stated below. This group normally includes associate deans, division heads, and department heads. The budget administrator approves transactions at the specified dollar levels and categories, affirming the programmatic need for the action and that the action is appropriate within University Policies and Guidelines.

#### **PROCEDURE:**

1. Anyone having reason to believe that a member of the faculty, staff, or a member of the student body has engaged in misconduct in research or other scholarly activity should discuss the situation with his or her Budget Administrator or Budget Executive, or the Vice President for Research. Allegations may be the result of misinterpreted communication or misunderstanding and therefore, they may be subject to resolution on a collegial basis, through discussion(s) designed to ascertain whether there is reason to believe that research misconduct may have occurred in violation of this policy. If the results of such discussion(s) confirm the possibility of research misconduct in violation of this policy, the matter should be reported, in writing, to the Vice President for Research. Upon receipt of written allegations of research misconduct, the Vice President for Research shall promptly provide a copy of such written allegations to the Budget Executive and Budget Administrator of the area in which the accused individual is primarily employed, and the Director of The Office For Research Protections. In addition, the Vice President for Research shall notify the accused individual of the alleged violation(s) of University policy.

The foregoing procedure shall also be followed in the event that an investigatory Committee appointed in accordance with Section 5 hereof obtains information that any individual, other than the one initially under investigation, has allegedly engaged in research misconduct.

2. Upon receipt of the written allegation(s) of research misconduct, the Vice President for Research, the Director of the Office for Research Protections, and the Budget Executive of the area in which the accused individual is primarily employed, in consultation with the Budget Administrator of the area in which the accused individual is primarily employed, shall immediately conduct an inquiry and shall take all necessary steps to protect government or industrial research funds and insure that the purpose of the Federal and industrial support are being carried out. If an emergency situation arises (e.g., illness, out of the country, etc.) that prevents the Budget Executive or Budget Administrator to participate in all or part of the inquiry, the Vice President for Research shall appoint an appropriate replacement. Relevant research records, documents, and/or materials shall be immediately sequestered. If the person(s) designated to conduct the inquiry does not have the necessary and appropriate technical expertise or background in the field of question, technical consultants (from within the University whenever possible) should also be appointed to assist in the inquiry. The inquiry must be completed within 60 calendar days of its initiation unless circumstances clearly warrant a longer period (up to 30 additional days). The Vice President for Research shall provide written notice to the accused individual that an inquiry shall be conducted as to specified allegation(s) of research misconduct. Precautions against real or apparent conflict of interest shall be taken, including, if necessary, referral by the Vice President for Research to another University officer or third party.

The privacy of the accused and the accuser, and the confidentiality of information shall be protected to the maximum extent possible.

3. A written report shall be prepared that states what evidence was reviewed, a copy of all interview transcripts and/or summaries, and includes the conclusions of the inquiry. The accused individual(s) shall be given a copy of the report of inquiry. If they comment on that report, their comments may be made part of the record. If the

inquiry takes longer than 60 days to complete, the record of inquiry shall include documentation of the reasons for exceeding the 60 day period.

4. Documentation in sufficient detail to permit a later assessment, if necessary, of the reasons for determining that an investigation was not warranted shall be maintained for a period of at least three years by the Vice President for Research, and shall be made available upon request to any involved Federal agencies.
5. If it is determined from the inquiry that the research misconduct allegation(s) warrant further investigation, the Vice President for Research, shall;
  - a. in consultation with the Budget Executive and Budget Administrator of the area in which the accused individual is primarily employed, appoint an ad hoc Investigatory Committee composed as provided herein,
  - b. refer the research misconduct charge to the Committee,
  - c. take such interim action as may be necessary to ensure the integrity of research or other scholarly work, the rights and interests of research participants and the public, and the observance of legal requirements or responsibilities, and
  - d. provide written notification to the accuser and the accused individual of the initiation of the investigation and of the misconduct allegation(s) to be investigated.

Thereafter, the Director of The Office For Research Protections shall provide on-going administrative support and assistance to the investigatory committee.

6. The Committee shall consist of at least five tenured University faculty members, each of whom should have no conflict of interest and be competent, in the judgment of the Vice President for Research, to evaluate the questions before the Committee. External scholars or persons with relevant expertise may be consulted by the Committee where warranted by the nature of the field or by the nature of the allegation(s).
7. Within 30 days of the completion of the inquiry, the Committee shall initiate and conduct a prompt and thorough investigation in order to ascertain the facts of the case and to determine whether the accused individual has violated University policy. The Committee shall provide the accused individual the opportunity to be heard by the Committee, through presentation of statements and/or documents with respect to the research misconduct allegation(s), as the accused person prefers.
8. The investigation normally will include examination of all documentation, including but not necessarily limited to relevant research data and proposals, publications, correspondence, and memoranda of telephone calls. Whenever possible, interviews should be conducted of all individuals involved, including the accused and the accuser(s), as well as other individuals who might have information regarding key aspects of the allegations; complete summaries of these interviews should be prepared, provided to the interviewed party for comment or revision, and included as part of the investigatory record.
9. Upon conclusion of the investigation, the Committee shall prepare a preliminary investigation report setting forth its findings with respect to the research misconduct allegation(s) and the grounds on which such findings were based. A copy of the preliminary investigation report and a copy of all interview transcripts and/or summaries shall be provided to the accused individual, who shall be permitted to present a written response to said report within fourteen days. Upon expiration of the fourteen-day response period, the Committee shall prepare a final investigation report.
10. Requirements for a finding of misconduct (42 Code of Federal Regulations, Part 93.104):
  - a. There must be a significant departure from accepted practices of the relevant research community;
  - b. The misconduct must have been committed intentionally, knowingly, or recklessly;
  - c. The allegation must have been proven by a preponderance of the evidence.
11. If a majority of the Committee finds that the individual has violated University policy and committed misconduct, it shall recommend an appropriate course of action to the Vice President for Research, which may include disciplinary sanctions and which shall include adequate steps to ensure that the University meets its obligations, if any, to third parties affected by the violation; these third parties shall include co-investigators and coauthors, granting agencies and other research sponsors, professional journals and relevant clients.

12. The Vice President for Research shall consider the Committee's findings and recommendations, and in consultation with the Budget Executive and Budget Administrator of the area in which the accused individual is primarily employed, prepare a written decision upholding or rejecting, in whole or in part, the findings and recommendations in the Committee's final investigation report. The Vice President for Research shall provide a copy of the written decision to the accused individual.
- a. If the Vice President for Research finds University policy has been violated based on the preponderance of the evidence, he or she shall;
    - i. take all appropriate actions to ensure that the University meets its obligations to all parties affected by the violation, and;
    - ii. notify the Budget Executive and Budget Administrator of the area in which the accused individual is primarily employed, in writing, of the actions to be taken and will notify all affected parties.
  - b. If the Vice President for Research finds University policy not to have been violated, either at the inquiry stage or after a full investigation, these proceedings will be closed and the accused individual and the accuser so notified in writing. Diligent efforts should be undertaken, as appropriate, to restore the reputations of the accused when allegations are not confirmed, and also diligent efforts should be undertaken to protect the positions and reputations of those who, in good faith, make allegations of research misconduct.
- Throughout these proceedings, the privacy of the accused and the accuser, and the confidentiality of the information related to the proceedings shall be protected to the maximum extent possible.
13. If an investigation is undertaken pursuant to this policy, the investigation should normally be concluded, and a decision made by the Vice President for Research, within 120 days from the initiation of the investigation.
14. All records related to research and scholarly ethics investigations shall be retained in the Office of the Vice President for Research for a minimum of ten (10) years.

#### **REPORTING TO THE SPONSOR:**

The Vice President for Research shall take steps to notify, and keep informed, research sponsors in compliance with applicable laws, regulations and agreements. In particular, research sponsors shall be:

- a. informed immediately in writing if an initial inquiry supports a formal investigation;
- b. kept informed during such a formal investigation;
- c. notified immediately, or as required during an inquiry or investigation;
  - i. if the seriousness of apparent research misconduct warrants,
  - ii. if immediate health hazards are involved,
  - iii. if the research sponsor's resources, reputation, equipment, or other interests require protection,
  - iv. if Federal action may be needed to protect the interest of a subject of the investigation or of others potentially affected,
  - v. if the scientific community or the public should be informed, or
  - vi. if there is reasonable indication of possible criminal violation, in which event notification must be made within 24 hours of obtaining that information.

The Vice President for Research will notify other outside parties as may be appropriate, including publishers or institutions with whom the individual found to have committed research misconduct is now or has been professionally affiliated.

If the sponsor is the Department of Health and Human Services, the Director of the Office of Research Integrity (ORI) must be notified within 24 hours of obtaining any reasonable indications of possible criminal violations. If an investigation cannot be completed within 120 days, a written request for an extension must be submitted to ORI including an explanation for the delay that includes an interim report on the progress to date. If an inquiry or an investigation is planned to be terminated prior to completion, a written report of such planned termination, including a description of the reasons for such termination, shall be made to the Director of ORI.

Where applicable, all documentation substantiating the findings hereunder shall be made available to the Federal agency involved, and in the case of HHS, to the Director of ORI.

#### **CROSS-REFERENCES:**

Other Policies in this Manual should also be referenced, especially the following:

[RA11](#) Patents and Copyrights (Intellectual Property)  
[RA12](#) Technology Transfer and Entrepreneurial Activity (Faculty Research)  
[RA14](#) The Use of Human Participants in Research

Effective Date: May 21, 2007  
 Date Approved: May 17, 2007  
 Date Published: May 18, 2007 (editorial changes February 24, 2010)

#### **Most Recent Changes:**

- February 24, 2010 - Editorial changes. Changed the title of "Senior Vice President for Research and Dean of the Graduate School" TO "Vice President for Research," along with capitalizing Budget Executive and Budget Administrator references, where necessary. Updated links and other policy titles throughout the policy.

#### **Revision History (and effective dates):**

- January 1, 2010 - Editorial changes. Title changed FROM "Senior Vice President for Research and Dean of the Graduate School" TO "Vice President for Research and Dean of the Graduate School," to reflect position changes, effective January 1, 2010.
- November 7, 2007 - Editorial changes; revised title in "Definitions" section- changed "Campus Executive Officers" to "Chancellors."
- May 21, 2007 - Revisions to the POLICY, DEFINITIONS and PROCEDURES sections to clarify the handling of inquiries and investigations.
- November 8, 2006 - Editorial change - changed Vice President for Research to Senior Vice President for Research.
- November 11, 2003:
  - Purpose revised to emphasize ethic related to research and other scholarly activities.
  - Under the DEFINITIONS section: changed "misconduct" to "research misconduct" and updated the definition thereof; added a definition for "allegation."
  - For the reporting and oversight of misconduct investigations, changed "budget administrator" to "Vice President for Research."
  - Provided for sequestering of relevant documents and records.
  - Other editorial clarifications.
- February 20, 1998 - Relocating and renumbering Policy RA10 from AD04, and updated RA11, RA12, and RA14 locations.

## APPENDIX A 4

### Research Administration Policy RA13

#### CO-AUTHORSHIP OF SCHOLARLY REPORTS, PAPERS AND PUBLICATIONS

<http://guru.psu.edu/policies/ra13.html>

##### Contents:

- [Purpose](#)
- [Guidelines](#)
- [Cross References](#)

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##### PURPOSE:

It is the policy of The Pennsylvania State University that proper credit be given to those individuals who make material contributions to activities which lead to scholarly reports, papers and publications.

##### GUIDELINES:

Rigid prescriptive requirements in this area are considered unwise, because the situation with respect to co-authorship varies from one discipline to another and from one publication to another. Nevertheless, it is recommended that the authors of scholarly reports, papers and publications abide by the following principles regarding co-authorship.

(1) Co-authorship should be offered to anyone who has clearly made a material contribution to the work.

Moreover, each coauthor should be furnished with a copy of the manuscript before it is submitted, and allowed an opportunity to review it prior to submission. An author submitting a paper, report or publication should never include the name of a coauthor without the person's consent. Exceptional circumstances, such as death or inability to locate a coauthor, should be handled on a case by case basis. In cases where the contribution may have been marginal, an acknowledgment of the contribution in the public action might be more appropriate than co-authorship.

(2) In cases of theses for advanced degrees, if any publication derived from the thesis is not published with the degree recipient as sole author, then that person should be listed as coauthor. In no instance should publications derived from a thesis be published under the sole authorship of the thesis adviser.

(3) Anyone accepting co-authorship of a paper must realize that this action implies a responsibility as well as a privilege. As a general rule, each coauthor should understand the content of the publication well enough to be able to take responsibility for all of it; otherwise, the publication should clearly indicate the parts of which each coauthor has responsibility. If a potential coauthor has doubts concerning the correctness of the content or conclusions of a publication, and if these doubts cannot be dispelled by consultation with the other coauthors, the individual should decline co-authorship.

##### CROSS REFERENCES:

Other policies may also be referenced, especially the following:

[AD47](#) - General Standards of Professional Ethics.

[RA10](#) - Handling Inquiries/Investigations into Questions of Ethics in Research and in Other Scholarly Activities

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Effective Date: May 23, 2007  
Date Approved: May 17, 2007  
Date Published: May 22, 2007 (editorial changes February 25, 2010)

**Most Recent Changes:**

- February 25, 2010 - Minor editorial changes made throughout the policy.

**Revision History (and effective dates):**

- May 23, 2007 - Revisions to Guideline #2, to clarify publishing particulars involving theses for advanced degrees.
- February 20, 1998 - Relocated and renumbered Policy RA13 from AD48, and updated RA10 location.

## APPENDIX A 5

### Research Administration Policy RA14

#### THE USE OF HUMAN PARTICIPANTS IN RESEARCH

<https://guru.psu.edu/policies/RA14.html>

##### Contents:

- [Purpose](#)
- [Policy](#)
- [Definitions](#)
- [Applicability](#)
- [Authority of the IRB](#)
- [Types of Review](#)
- [IRB Application Procedure](#)
- [Other Institutions](#)
- [Regulatory Agencies](#)
- [Research Agreement, Financial Information and Conflict of Interest](#)
- [Principal Investigator Responsibilities](#)
- [Cross References](#)

##### PURPOSE:

The Pennsylvania State University (PSU) is positively and unequivocally committed to the promotion, encouragement, and facilitation of academic and clinical research in the broad area of general or specific measurements of human development, health, and performance. PSU is dedicated to the ethical treatment of human participants in all research activities conducted under the auspices of this institution and assumes responsibility for safeguarding their rights and welfare. The purpose of this policy is to outline PSU's standards for the protection of human participants of research.

##### POLICY:

PSU's policy for the protection of human participants is guided by ethical principles, Federal law, and institutional standards. The guiding ethical principles are embodied in the Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.htm>). Compliance with this policy provides protections for human participants as mandated by applicable laws, regulations, and standards of local, state and Federal government agencies concerning the protection of human participants, including the U.S. Code of Federal Regulations (CFR):

- Title 45 CFR 46, Protection of Human Subjects, U.S. Department of Health and Human Services (DHSS), Office for Human Research Protections (OHRP) (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm>) and
- Title 21 CFR 50, 56, 312, 600 and 812 of the Food and Drug Administration (FDA) (<http://www.fda.gov/oc/ohrt/irbs/>)

PSU's policy for the protection of human participants also meets high institutional standards in its ethical principles and regulations. Institutional requirements are mandated for all research, not just federally funded research.

The Institutional Review Board (IRB) is a specifically constituted administrative review board established for the purpose of protecting the rights and welfare of human participants who are recruited to participate in research. The jurisdiction of the IRB relates to the institution with which it is affiliated.

An Assurance is kept on file with the Department of Health and Human Services' (DHHS) Office for Human Research Protections (OHRP) covering all PSU colleges and campus locations, with the exception of the College of Medicine (COM), which maintains a separate Assurance with OHRP. These Assurances set forth the policies for the protection of human participants, and include the duties and procedures of the IRBs.

PSU-related research, as defined by 45 CFR 46 and 21 CFR, 50, 56, 312, 600, and 812, involving human participants directly or through the use of records, tissues, or other indirect means must receive prior review and approval before any project can begin. Research involving human participants may not be conducted within or on behalf of PSU without prior review and approval of the project prior to involving human participants.

Thus, the IRB is the final authority for safeguarding, as defined by 45 CFR 46 and 21 CFR, 50, 56, 312, 600, and 812, research involving human participants. Failure to have research involving human participants reviewed and approved by the IRB is a violation of PSU policy, Federal regulations, and the Assurance. In addition to review by the IRB, research may be subject to further appropriate review and approval or disapproval by the officials of the institution; however, those officials may not override a decision by the IRB to disapprove research.

#### **DEFINITIONS:**

This policy defines “human research” or “research involving human participants” as any activity that meets the DHHS definition of “research” which involves persons who meet the DHHS definition of “human participant,” OR any activity that meets the FDA definition of “research” which involves persons who meet the FDA definition of “human participant.”

“**Research**” under the DHHS regulations means a “systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge” (45 CFR §46.102[d]) (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102>).

“**Human participant**” under the DHHS regulations means a “living individual about whom an investigator (whether professional or student) conducting research obtains: (1) data through intervention or interaction with the individual or (2) identifiable private information” (45 CFR §46.102[f]) (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102>). Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the participant or the participant’s environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and participant. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individual identifiable (i.e., the identity of the participant is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human participants.

“**Research**” under the FDA regulations means any experiment that involves a test article and one or more human participants and that either is subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or is not subject to requirements for prior submission to the FDA under these sections of the act, but the results of which are intended to be submitted later to, or held for inspection by the FDA as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study and clinical investigation are deemed synonymous for purposes of the FDA regulations (21 CFR §56.102[c]) (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=56.102>). In practice, all uses of drugs or medical devices constitute “research” under this definition unless the drug or device is both approved and being used in the course of medical practices. In addition, all uses of FDA-regulated test articles in which the results will be submitted to the FDA or held for inspection by the FDA constitute “research” under this definition.

“**Human participant**” under the FDA regulations means an individual who is or becomes a participant in research, either as a recipient of a test article or as a control. For medical device studies in which data will be submitted to the FDA or held for inspection by the FDA, a human participant includes a human on whose specimen an investigational device is used.

“**Minimal risk**” means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45 CFR §46.102[i]) (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.102>).

“**Research Agreement**” is defined as the mutually binding legal document between the funding entity and the University specifying the terms and obligations under which the externally-funded project services will be conducted.

#### **APPLICABILITY:**

Research conducted at PSU includes both biomedical research and social science research. Due to the large volume and diverse nature of research conducted at PSU, multiple IRBs have been established in order to provide the review



and oversight for all research involving human participants. The committee members are appointed by the Vice President for Research or the Associate Vice President for Health Sciences Research to recommend and implement policies and regulations for the protection of human participants in research.

1. PSU has established two IRBs located at the University Park Campus: (a) the Social Science IRB and (2) the Biomedical IRB. These IRBs review all of the research conducted by investigators from all PSU colleges and campus locations except the COM.
2. Penn State's College of Medicine located at the Penn State Milton S. Hershey Medical Center (PSHMC) has established four IRBs to review and provide oversight for biomedical and social science research projects conducted at the COM and PSHMC. PSHMC has a separate Assurance with OHRP and has designated the COM IRBs for the review of research under this Assurance. PSHMC has a written agreement with the COM documenting this reliance on the COM IRBs.

#### **AUTHORITY OF THE IRB:**

The IRB has the authority to review all human participant research regardless of funding, including the categories exempted or waived by OHRP or FDA regulations, provided that one or more of the following apply to all or part of the research:

- The research is sponsored by PSU or PSHMC; or
- The research is conducted by or under the direction of any employee or agent of PSU or PSHMC in connection with his or her institutional responsibilities; or
- The research is conducted by or under the direction of any employee or agent of PSU or PSHMC using any property or facility of PSU or PSHMC; or
- The research involves the use of PSU's or PSHMC's non-public information to identify or contact human research participants or prospective participants.

The IRB has the authority to:

- Approve, require modification to secure approval, disapprove all research activities overseen and conducted by the organization;
- Suspend or terminate IRB approval of research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected serious harm to participants;
- Observe, or have a third party observe, the consent process; and
- Observe, or have a third party observe, the conduct of the research.

The IRB will review research performed by PSU or PSHMC employees and students at other institutions or sites, and research performed at PSU or PSHMC by investigators who are not affiliated with PSU or PSHMC. When research reviewed by the IRB is conducted at or in cooperation with another entity, all requirements of the IRB review will remain in effect for that research.

The IRB will review and approve research conducted outside the United States of America by PSU or PSHMC employees or students even if the foreign research receives no U.S. government funding. Such collaborative research activities must meet high ethical standards similar to those required within this policy. The IRB may approve such research, provided it determines that (a) the research conforms to proper codes of ethics (e.g., the Declaration of Helsinki or the Belmont Report), and (b) the research is approved by the foreign research site's ethical review authority. Requirements for the informed consent process will follow the laws and customs of the country in which the research is being conducted. If a U.S. Department or Agency funds the research, then it is probable that the foreign research site will need to file an FWA application. Instructions and templates for foreign research are available from OHRP (Assurances and IRB Registration at <http://www.hhs.gov/ohrp/>).

#### **TYPES OF IRB REVIEW:**

Three levels of IRB review/approval for research involving human participants have been established: (1) FULL BOARD REVIEW, (2) EXPEDITED REVIEW, and (3) EXEMPT REVIEW. Each type of review is specifically defined in the Federal regulations. The PSU IRBs must follow these specifications for designating the review type to remain in compliance with the Assurances. For additional information, please see <http://www.research.psu.edu/orp/areas/humans/reviewtypes.asp>.

Full Board Review - All projects involving human participants exposed to greater than minimal risks (including all research that exposes the participant to x-rays and/or microwaves) must be submitted for review by the IRB at a convened meeting. Such projects require submission of the application form, informed consent/assent form(s), and

supporting documents (e.g., protocol documents, recruitment material, questionnaires, surveys, investigator brochures and grant proposals [if applicable]).

Following initial review and approval by the IRB at a convened meeting, investigators conducting research designated by the IRB as Full Board Review are required to do the following:

- have all modifications to the research protocol reviewed and approved by the IRB prior to instituting them;
- report to the IRB problems that require prompt reporting (see “Standard Operating Procedures on Reporting of Unanticipated Problems Involving Risks to Participants or Others”);
- maintain IRB approval until data collection and analysis is complete and all research activity has ceased;
- submit reports/information to the IRB as requested; and
- submit progress reports at intervals stipulated by the IRB (including a final report to the IRB upon completion of the data collection and analysis).

Expedited Review - All projects involving human participants exposed to no more than minimal risk, as defined above, or to no risk (e.g., existing record review, use of existing pathology, surveys) AND that are included on the list of types of research designated by Federal regulations as qualifying for expedited review may be approved through the expedited review process (45 CFR 46.110) (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.110>). Such projects do NOT have to wait for a convened meeting of the full IRB, but may be reviewed and approved by the IRB chair or his/her designee, and reported to the IRB at a convened meeting. These projects require submission of the application form, informed consent/assent form(s) (if applicable), and supporting documents (e.g., protocol documents, recruitment material, questionnaires, surveys, and grant proposals [if applicable]).

Following initial review and approval by the IRB Chair or Chair's designee, investigators conducting research designated by the IRB as qualified for expedited review are required to do the following:

- have all modifications to the research protocol reviewed and approved by the IRB prior to instituting them;
- report to the IRB problems that require prompt reporting (see “Standard Operating Procedures on Reporting of Unanticipated Problems Involving Risks to Participants or Others”);
- maintain IRB approval until data collection and analysis has been completed, and all research activity has ceased;
- submit reports/information to the IRB as requested; and
- submit progress reports at intervals stipulated by the IRB (including a final report to the IRB upon completion of the data collection and analysis).

Exempt Research - Certain types of research may be found by the IRB to be exempt from IRB oversight (45 CFR 46.101[b]) (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101>). At PSU, investigators may not make an independent determination that research involving human participants is exempt from Federal regulations. Only a designated IRB member or qualified staff from the Office for Research Protections or Human Subjects Protection Office has the authority to make this determination following review of a research application, informed consent form if applicable, and supporting documents (e.g., recruitment materials, questionnaires/surveys, and grant proposals, [if applicable]). Investigators conducting research designated at the exempt level are required to submit modifications that may affect the exempt status for review prior to instituting the proposed changes.

Some studies may not meet the definition of “research” and/or a “human participant.” However, investigators may not make an independent determination that their study does not meet the definition of “research” and/or “human participant.” Only qualified staff from the Office for Research Protections or Human Subjects Protection Office has the authority to make this determination.

#### **IRB APPLICATION PROCEDURE:**

The most current applications for human participant research are available at the following locations: the Office for Research Protections, University Park Campus (<http://www.research.psu.edu/orp/>) or the Human Subjects Protection Office, and College of Medicine (<http://www.hmc.psu.edu/irb/>). Completed forms and other required materials as indicated on the application should be returned to the appropriate IRB administrative office.

#### **OTHER INSTITUTIONS:**

The IRB interacts with other institutions to ensure that IRB policies and procedures are followed when PSU or PSHMC employees and students perform research at other institutions, or when personnel or students from other institutions perform research at PSU or PSHMC facilities.

The IRB may agree to permit another federally sanctioned IRB to serve as the IRB of record for studies to be conducted by, or with the assistance of PSU personnel, at the facilities of a second institution. The IRB may agree to function as the IRB of record for another investigator and/or institution if the project involves material collaboration from PSU personnel. Such agreements will require written letters of agreement and may include the completion of additional documentation under the Federal-wide Assurance process. Copies of these agreements will be maintained at the respective administrative area.

#### **REGULATORY AGENCIES:**

As required by Federal regulations and by the Assurances, the IRB will contact directly the appropriate governmental authority at OHRP and/or FDA regarding questions or to notify them of reportable events, such as unanticipated problems involving risks to participants or others, serious or continuing investigator non-compliance, or termination or suspension of IRB approval of research protocols.

#### **RESEARCH AGREEMENT, FINANCIAL INFORMATION AND CONFLICT OF INTEREST:**

The research agreement and financial information related to sponsored research, such as project budget, schedule of payments to PSU and human participants, arrangements for medical care for research-related injury, and monetary or other enrollment incentive/bonus payments, if offered, must be submitted to the Office of Sponsored Programs at the University Park Campus or the Office of Research Affairs at College of Medicine for review (see [RA16](#)). If, as the project progresses, there are changes in financial arrangements, medical care for research-related injury arrangements, or a sponsor decides to institute incentive/bonus offers, these new arrangements must be submitted to the Office of Sponsored Programs or the Office of Research Affairs for review and approval prior to instituting these changes. For federally funded projects, see [RA04](#) - Making Revisions to Budgets and Program Plans on Federally Sponsored Projects. It is the policy of PSU that neither it, nor its investigators, or other study personnel, will accept unauthorized incentives or bonuses tied to the rate of recruitment of project participants or to early enrollment of participants in clinical trials, whether such incentives or bonuses are offered as a part of a research agreement or at any other time. For the purposes of this policy, the terms, incentives, or bonuses include anything of value.

In accordance with PSU Policy [RA20](#)- Individual Conflict of Interest and [HR91](#)- Conflict of Interest, all project personnel must apprise the IRB of any significant financial or business interest. The term "Significant Financial or Business Interest" is defined in Policy [RA20](#). Final IRB approval for any project will be withheld pending disclosure, management and/or resolution of any conflict-of-interest issues to the satisfaction of the IRB.

**NOTE:** For the purposes of this item, "project personnel" includes, but is not limited to, the principal investigator, co-investigators, study coordinators, research collaborators, or any other provider of direct services or participant care.

#### **PRINCIPAL INVESTIGATOR RESPONSIBILITIES:**

The Principal Investigator (PI) is the individual responsible for the implementation of research. The IRB recognizes one PI for each project. All official IRB correspondence is addressed to the PI. Co-investigators communicate with the IRB through the PI. The PI has the ultimate responsibility for his/her research project by:

- Acknowledging and accepting his/her responsibility for protecting the rights and welfare of human research participants and for complying with all applicable Federal, state, and local regulations, as well as PSU policies regarding research with human participants;
- Ensuring that a project is designed to minimize risks to participants while maximizing research benefits;
- Ensuring that all members of the research team know and understand the research project and they comply with the findings, determinations, and requirements of the IRB;
- Ensuring the adequacy of both the informed consent form and the informed consent process;
- Ensuring that all human participant research that he/she conducts receives initial prospective review and approval by the IRB;
- Ensuring that continuing review and approval of the research has been accomplished within the time frame stipulated by the IRB;
- Ensuring that no changes in approved research are initiated without prior IRB review and approval, except where necessary to eliminate apparent immediate hazards to participants;
- Ensuring that no research is continued beyond the IRB designated approval period;
- Notifying the IRB promptly of:

o Any significant problems that require prompt reporting to the IRB according to the IRB policy "Reporting of Unanticipated Problems Involving Risks to Participants or Others;" and;

o Any suspected non-compliance as described in the IRB policy on the "Handling of Allegations of Non-compliance" with applicable regulatory requirements or determinations of the IRB of which he/she becomes aware.

For additional information, contact:

Office for Research Protections Penn State University 201 Kern Building University Park, PA 16802 (814) 865-1775	<b>OR</b>	Human Subjects Protection Office Penn State University COM 500 University Drive, Mail Code H112 Hershey, PA 17033-0850 (717) 531-5687
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This policy is reviewed and approved by the Vice President for Research & Dean of the Graduate School.

#### **CROSS REFERENCES:**

AD19 - Use of Penn State Identification Number and Social Security Number,

AD47 - General Standards of Professional Ethics,

HR91 - Conflict of Interest,

RA04 - Making Revisions to Budgets and Program Plans on Federally Sponsored Projects,

RA10 - Handling Inquiries / Investigations into Questions of Ethics in Research and in Other Scholarly Activities,

RA16 - Administration of Sponsored Project Contract and Subcontracts of the University,

RA20 - Individual Conflict of Interest,

RA21 - Institutional Financial Conflict of Interest Involving Sponsored Projects, Dedicated Gifts, Research, Scholarship, and Technology Transfer

Procedure CR2078, Payment to Research Participants

Effective Date: June 17, 2009

Date Approved: June 15, 2009

Date Published: June 16, 2009

#### **Most recent changes:**

- June 17, 2009 - Revisions made in all sections of the policy to provide clarification and more detail about the process and definitions. Title changed from "The Use of Human Subjects in Research" to "The Use of Human Participants in Research."

#### **Revision History (and effective dates):**

- September 12, 2005 - Major revisions, developed collaboratively with the College of Medicine, and with input from the Office of Sponsored Programs (UP) and the Office of Research Affairs (College of Medicine):

Expanded "Contents," with the following sections added:

- Authority of the Institutional Review Board (IRB)
- Types of Review
- Other Institutions
- Regulatory Agencies
- Research Agreement, Financial Information and Conflict of Interest

- Principal Investigator Responsibilities
- Cross References "
  
- February 20, 1998 - Relocated and renumbered Policy RA14 from SY22

## APPENDIX A 6

### Research Administration Policy RA15

#### CARE AND USE OF VERTEBRATE ANIMALS

<https://guru.psu.edu/policies/RA15.html>

##### Contents:

- [Purpose](#)
  - [Policy](#)
  - [Applicability](#)
  - [Exclusions](#)
  - [Definitions](#)
  - [Submission Procedure](#)
  - [Biohazardous Agents and Radioisotopes in Animals](#)
  - [Cross References](#)
- 

##### PURPOSE:

This policy provides the following assurances:

1. Vertebrate animals involved in any research, testing or teaching procedures receive humane care and treatment.
2. Animal research is conducted in a well-controlled research environment.
3. Concerns regarding the care and use of vertebrate animals at the University are addressed in a professional and responsible manner.
4. Research involving the use of live animals is performed in an ethical manner, designed to minimize pain and distress, and comply with applicable federal and state regulations.

This policy enacts certain necessary provisions of the University's "Assurance of Compliance with Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals," an agreement with the Office for Laboratory Animal Welfare (OLAW) at the National Institutes of Health (NIH) which provides eligibility for receipt by University investigators of funding from various federal agencies.

##### POLICY:

Approval by the University's Institutional Animal Care and Use Committee (IACUC) is required prior to the actual involvement of a vertebrate animal in any University research, testing or teaching procedures. Any such project involving an external sponsor must be reviewed and approved by the IACUC before funding is accepted.

IACUC records are subject to regular unannounced inspections by representatives of the United States Department of Agriculture (USDA). USDA inspection reports describe any institutional deficiencies or apparent IACUC record violations, and are accessible to the public under the Freedom of Information Act. For this reason, all IACUC submissions must be carefully prepared and detailed; a written memo must document all submission supplements or clarifications. The Office for Research Protections (ORP) in The 330 Building, Suite 205 (865-1775), is responsible for coordinating IACUC reviews and approvals.

Concerns regarding the proper care and use of vertebrate animals in a University project are to be reported to the ORP, investigated by the IACUC and resolved in a timely manner.

##### APPLICABILITY:

This policy is applicable to all research, testing or teaching activities involving vertebrate animals (live or dead\*) or animal parts except as excluded below, conducted under the auspices of the University and applies to all University locations, excluding the College of Medicine at Hershey which maintains a separate animal welfare assurance with OLAW. University projects involving the use of vertebrate animals at other institutions must receive IACUC approvals from both the cooperating institution and Penn State University. The College of Medicine at Hershey Medical Center will serve as

the cooperating institution during a collaborative effort between the College of Medicine at Hershey Medical Center and any other University location.

\* The IACUC reviews the use of dead animals to verify that they originate from a reputable source and are disposed of appropriately.

#### **EXCLUSIONS:**

The following materials are excluded from this policy and are exempt from IACUC review:

1. Animal tissues or parts collected from animals euthanized under an approved IACUC protocol.
2. Animal tissues or parts collected from USDA inspected slaughter houses.
3. Established cell lines, as well as biological fluids and foods available as standard inventory from a conventional commercial supplier

#### **DEFINITIONS:**

##### **Vertebrate Animal --**

Penn State University defines an animal as being any non-human organism possessing a well-developed nervous system as characterized by the presence of a dorsal notochord protected by a vertebral column. This policy applies to non-human vertebrate animals, live or dead.

##### **IACUC--the Institutional Animal Care and Use Committee --**

This committee is appointed to review all proposed research, testing or teaching activities involving vertebrate animals to be conducted under the auspices of the University. Projects are reviewed for compliance with the principals of humane animal care and use as set forth by policies and regulations promulgated by the United States Department of Agriculture and the Public Health Service. The membership of this committee provides for a balanced review of all submitted activities by inclusion of veterinarians, faculty, staff, and local community representatives.

#### **SUBMISSION PROCEDURE:**

Submission forms can be obtained from the [ORP WEB site](#). Completed forms should be returned to the ORP, The 330 Building, Suite 205, University Park, PA 16802. Copies of submissions received by ORP will be circulated to IACUC committee members.

The IACUC has final authority to disapprove or suspend indefinitely an activity involving the use of vertebrate animals.

Appeals will be heard by the IACUC; however, by federal law the IACUC has final authority and disapprovals cannot be overruled by any administrator at the University.

#### **BIOHAZARDOUS AGENTS AND RADIOISOTOPES IN ANIMALS:**

Any IACUC submission involving a biohazardous agent or radioisotope also will require prior approval by the Institutional Biosafety Committee or the University Isotopes Committee, respectively. The investigator is to include, in the IACUC submission, a safety protocol describing procedures for work with biohazardous materials used with animals. The University Biosafety Officer, in consultation with animal care personnel, will aid investigators in designing appropriate safety protocols for the handling and disposal of animals contaminated with biohazardous materials. The University Health Physicist will advise investigators in the development of safety protocols involving the use of radioisotopes.

Approved by the Institutional Animal Care and Use Committee on March 22, 2004

#### **CROSS REFERENCES:**

Other Policies in this Manual should also be referenced, especially:

[SY20](#) - Hazardous Waste Disposal, and

SY24 - Use of Biohazardous Materials in Research and Instruction.

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Effective Date: May 24, 2007

Date Approved: May 17, 2007

Date Published: May 23, 2007 (Editorial changes, August 12, 2010)

**Most recent changes:**

- August 12, 2010 - Editorial changes made; updated address and website links were revised in the POLICY and SUBMISSION PROCEDURE sections, respectively.

**Revision History (and effective dates):**

- May 24, 2007 - Major revisions to entire policy, as approved by the Institutional Animal Care and Use Committee (IACUC).
- February 23, 2005:
  - Responsibility moved from Office for Protection from Research Risks to Office for Laboratory Animal Welfare.
  - Under the section BIOHAZARDOUS AGENTS AND RADIOISOTOPES IN ANIMALS, the procedure was rewritten.
  - Under the APPROVAL PROCEDURE, upon completion of the IACUC review, ORP prepares letters of approval for proposals.
  - Under the section DISAPPROVALS, "lack of availability of adequate animal housing or care" was changed to "inadequate animal housing or care."
  - Lack of compliance with federal regulations was added as a reason for disapproval.
  - Changes to several office names.
- February 20, 1998 - Relocated and renumbered Policy RA15 from SY23, and clarified "Exclusions."
- September 1, 1994 - Office addresses updated.
- March 24, 1992 - New policy.



## APPENDIX A 7

### Safety Policy SY24

#### USE OF REGULATED AND BIOHAZARDOUS MATERIALS IN RESEARCH AND INSTRUCTION

<https://quru.psu.edu/policies/SY24.html>

##### Contents:

- [Purpose](#)
  - [Applicability](#)
  - [Policy](#)
  - [Responsibilities](#)
  - [Definitions](#)
  - [Requests for Biohazards Reviews](#)
  - [Approval Procedure](#)
  - [Compliance](#)
  - [Cross References](#)
  - [Appendix A](#)
- 

##### PURPOSE:

To ensure safe handling, storage, and disposal of potentially biohazardous materials, as defined below, used in University research or instructional projects. Compliance with the provisions of this policy will provide a safe working environment, as well as protect the people and facilities of the larger University community and the surrounding areas. Institutional Biosafety Committee (IBC) review also assists the University and its employees in their compliance with federal regulations on the use of recombinant DNA, as well as federal and state regulations regarding pathogens, toxins, toxicants, and carcinogens.

##### APPLICABILITY:

This policy applies to any research and instructional activities, sponsored and unsponsored, conducted under the auspices of the University. This policy is applicable to all University locations (except the Hershey Medical Center which conducts independent biosafety committee reviews), and to research conducted off-site by University personnel. University projects involving the use of biohazardous materials at other institutions shall receive Institutional Biosafety Committee (IBC) approval from the cooperating institution. In the case of collaboration between the Hershey Medical Center and any other University location, Hershey will be treated as a cooperating institution. Copies of IBC approvals from cooperating institutions should be forwarded to the Office for Research Protections (ORP) along with a completed IBC application. The Penn State IBC may require approval from the cooperating institution prior to granting their approval.

##### POLICY:

All University research and instructional activities involving biohazardous materials, as defined below, shall be reviewed and approved by the Institutional Biosafety Committee (IBC) prior to the use of any such reagent. Projects submitted for sponsorship by external agencies should be submitted for IBC review prior to acceptance of funding. The Office for Research Protections (ORP), The 330 Building, Suite 205, University Park, PA 16802 (814-865-1775) coordinates IBC reviews and approvals. The IBC is vested with the right and authority to monitor the use of biohazardous material as approved hereunder.

##### RESPONSIBILITIES:

Budget executives and budget administrators shall ensure that all supervisors in their area are familiar with the provisions of this policy. Supervisors (department chairs, faculty and other employees with direct oversight of University employees and students) shall ensure that all University research is conducted in compliance with this policy. Employees and students shall ensure that their activities comply with any and all safety policies and procedures mandated by this policy.

**DEFINITIONS:****Regulated/Biohazardous Material -**

The categories below represent the areas of primary concern with respect to biosafety. Projects involving material(s) included by any of these categories should be submitted for IBC approval.

1. Chemical Carcinogens used in conjunction with animals.
2. Toxic/Infectious agents used in conjunction with animals.
3. Oncogenic viruses used in conjunction with animals.
4. Infectious agents requiring handling conditions above Biosafety Level-1. (Biosafety Level determinations are based on the recommendations outlined by the CDC-NIH publication [Biosafety in Microbiological and Biomedical Laboratories.](#))
5. Recombinant DNA.

Definitions For Clarification

- Recombinant DNA (rDNA) molecules are defined as either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) molecules that result from the replication of those described in (i) above.
  - Nucleic acids that are not and cannot be replicated inside organisms, cells, or viruses are not considered rDNA. Commonly encountered examples of synthetic DNA not considered to be rDNA include Polymerase Chain Reaction (PCR) products, synthetic oligonucleotides/primers, and complementary DNA (cDNA) obtained by reverse transcription of RNA.
6. Human or non-human primate blood and blood products, human or non-human primate body fluids, and/or human or non-human primate tissue.
  7. Toxins produced by living organisms (>1 mg of pure toxin, or solutions with concentrations of >1 mg/ml pure toxin). This provision excludes toxins covered by the Select Agent regulations (see #9).
  8. Whenever a contractual agreement or grant proposal requires Institutional Biosafety Committee approval for the safe handling of a biological or chemical product.
  9. HHS and USDA Select Agents and Toxins, as defined in Federal Regulations 7CFR331, 9CFR121, and 42CFR73, Additional Requirements for Facilities Transferring or Receiving Select Agents, Public Law 107-188, Public Health Security and Bioterrorism Response Act. The current list is available at <http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html>. These regulations also apply to nucleic acids that can produce infectious forms of any select agent virus, and recombinant nucleic acids that encode the functional forms of any select agent toxin.
  10. USDA Restricted Animal Pathogens, as determined by the United States Department of Agriculture (USDA), which are listed in [Appendix A](#).
  11. Wild Poliovirus or materials that may contain wild poliovirus [contact Environmental Health and Safety (814) 865-6391 for additional information on this subject].

The IBC also serves as an advisory committee for University projects that involve possible biohazards that do not appear to fall into one of the above areas. When it is unclear as to whether a material constitutes a potential biohazard, the IBC should be consulted. Questions should be directed to ORP or to Environmental Health and Safety at 6 Eisenhower Parking Deck.

**IBC--the Institutional Biosafety Committee -**

A Committee appointed by the Vice President for Research to review and approve the use of biohazardous materials in research. The membership of this Committee includes Penn State faculty and staff with expertise in relevant areas. In addition, at least two members of the local community are appointed to the committee to

represent local concerns. Membership of this Committee is consistent with federal regulations on the review of projects involving the use of recombinant DNA.

#### **REQUESTS FOR BIOHAZARDS REVIEWS:**

IBC submission forms can be obtained from the ORP web site. Completed forms should be returned via email to ORP-Biosafety@rtto.psu.edu. The Principal Investigator is responsible to provide sufficient information to allow the IBC to determine if this work can be conducted safely and appropriately.

A written safety protocol will be required for projects that involve biohazardous materials used in conjunction with animals, for project using Select Agents, for projects involving USDA Restricted Plant Pathogens, and for any project conducted at Biosafety Level 3 or higher. The safety protocol will require signatures from the Biosafety Officer and the appropriate facility manager.

#### **APPROVAL PROCEDURE:**

The IBC consists of the following subcommittees:

- Recombinant DNA
- Pathogens and Oncogenes
- Carcinogens and Toxins

Each IBC submission received by ORP will be pre-reviewed by the Compliance Coordinator and forwarded to a member of the appropriate IBC subcommittee(s). The subcommittee member will either approve the Application for the Use of Biohazardous Materials, and determine the appropriate biosafety requirements, request a second review by another member of the subcommittee, or schedule the project for consideration at the monthly meeting of the full IBC. In some instances, the PI may be asked to appear before the IBC. The Biosafety Officer will determine if a lab inspection is needed. Once the reviewer ballot and notification regarding the lab inspection are received from the subcommittee member and the Biosafety Officer, ORP will either issue an approval letter or request additional information. Additional information could consist of clarification of comments posed by the reviewer or the need for scheduling a lab inspection. The principal investigator will be responsible for responding to the request for additional information in a timely manner.

Once approval is granted, it is the responsibility of the PI to ensure that approval letters are properly directed to any funding agency or sponsor.

#### **COMPLIANCE:**

The IBC has express authority (1) to monitor research covered by approval letters it has issued; and (2) to enforce biosafety requirements, including the suspension of research, or recommending to the Vice President for Research and Dean of the Graduate School penalties and sanctions for non-complaint investigators. The IBC, through the Office for Research Protections, shall report such noncompliance to EH&S and may request their assistance in implementing sanctions, penalties, and/or suspensions.

#### **CROSS REFERENCES:**

Other Policies in this Manual should also be referenced, especially:

RA14 - The Use of Human Subjects in Research

RA15 - Care and Use of Vertebrate Animals

SY01 - Environmental Health and Safety Policy

SY14 - Use of Radioactive Materials

SY20 - Hazardous Waste Disposal.

**USDA Restricted Animal Pathogens/Diseases:**

- African horse sickness
- African Swine fever virus\*
- Akabane virus
- Avian Influenza virus
- Besnoitia besnoiti
- Bluetongue virus\*
- Bovine spongiform encephalopathy
- Bovine infectious patachial fever agent
- Brucella abortus
- Brucellosis melitensis\*
- Burkholderia mallei \* (Pseudomonas mallei - Glanders)
- Camelpox virus
- Classical Swine fever
- Cochliomyia hominivorax (Screwworm)
- Cowdria ruminantium (heartwater)
- Creutzfeldt-Jacob Disease variant
- Ephemeral fever virus
- Foot and mouth disease virus\*
- Histoplasma (Zyomonema) farciminosuim
- Louping ill virus
- Lumpy skin disease virus
- Mycobacterium bovis
- Mycoplasma agalactiae
- Mycoplasma mycoides (mycoides)
- Mycoplasma Capricolum/M.F38/M.
- Mycoides Carpi (Contagious Bovine Pleuropneumonia Agent)
- Nairobi sheep disease virus (Ganjam virus)
- Newcastle disease virus\* (velogenic strains)
- Peste des petits ruminants\* (plague of small ruminants)
- Rift Valley fever virus\*
- Rinderpest virus\*
- Sheep and goat pox\*
- Swine vesicular disease virus\*
- Teschen disease virus\*
- Theileria annulata
- Theileria lawrencei
- Theileria bovis
- Theileria hirci
- Trypanosoma brucei
- Trypanosoma congolense
- Trypanosoma equiperdum (dourine)
- Trypanosoma evansi
- Trypanosoma vivax
- Venezuelan equine encephalomyelitis
- Vesicular exanthema virus
- Vesicular stomatitis virus
- Viral hemorrhagic disease of rabbits
- Wesselsbron disease virus

\*Export license required by Department of Commerce

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Effective Date: May 10, 2011  
 Date Approved: May 4, 2011  
 Date Published: May 10, 2011

**Most recent changes:**

- May 10, 2011– Clarified responsibilities.

**Revision History (and effective dates):**

- January 1, 2010 – Editorial change made in "Compliance" section. Title changed FROM "Senior Vice President for Research and Dean of the Graduate School" TO "Vice President for Research and Dean of the Graduate School," to reflect position changes, effective January 1, 2010.
- March 11, 2009– Editorial changes made in "Definitions" section, adding 'non-human primate' to the materials defined in #6 which require IBC approval, in observance of biosafety requirements.
- November 11, 2008– Editorial changes have been made, as follows: policy title has been amended to include "Regulated" materials; DEFINITIONS section modified to include regulated materials, and #5 revised; link to SY14 added in CROSS REFERENCES section.
- October 24, 2007 – Added clarification on nucleic acids from select agent viruses and toxins, as approved by the University Biosafety Committee.
- November 8, 2006 - Editorial change - changed Vice President for Research to Senior Vice President for Research.
- September 27, 2005 - Procedures modified and link to Select Agent list added.
- December 5, 2002 - Definitions of Biohazardous Materials expanded and responsibilities added.
- September 1, 1994 - Updated office addresses and revised procedure for requesting biohazards reviews.

## APPENDIX A 8 Safety Policy SY20

### HAZARDOUS WASTE DISPOSAL

<https://guru.psu.edu/policies/SY20.html>

#### Contents:

- [Purpose](#)
- [Reference](#)
- [Definition](#)
- [Policy](#)
- [Reducing Hazardous Materials](#)
- [Responsibilities](#)
- [Procedures](#)
- .... [Collection and transportation of hazardous waste at University Park](#)
- .... [Disposal of hazardous waste at non-University Park locations \(except Hershey Medical Center\)](#)

#### PURPOSE:

To establish a policy and procedures for the handling, transportation and disposal of hazardous waste at all locations of The Pennsylvania State University (except the Hershey Medical Center).

Hazardous wastes may be generated by a variety of University activities such as teaching, testing and research laboratories, maintenance, housekeeping and agricultural operations. These wastes may cause severe illness or death or pose substantial environmental threats when improperly stored, transported, treated or disposed.

#### REFERENCE:

The University is required by regulation 25 PA Code Ch. 260 a - 262 a and by Environmental Protection Agency regulation 40 CFR 260-262 to ensure the proper disposition of these wastes.

#### DEFINITION:

A waste may be designated as a hazardous waste if it meets **one** of the following criteria:

1. Acute hazardous waste is a waste which has been found to be **fatal in humans** in low doses or, in the absence of data on humans, has been found to have, in laboratory animals:

- (A) an oral LD50 of less than 50 mg/kg,
- (B) an inhalation LC50 of less than 2 mg/l, or
- (C) a dermal LD50 of less than 200 mg/kg.

- A waste is hazardous if it contains any of the toxic constituents listed in the regulations.
- A waste is hazardous if it exhibits any of the following characteristics:

- (A) Ignitability
- (C) Reactivity
- (B) Corrosivity
- (D) Toxicity

#### POLICY:

The Senior Vice President for Finance and Business establishes and approves the policy and procedure for hazardous waste disposal within the environment of The Pennsylvania State University. The basis for such policy and procedure

shall be recommendations of the University Hazardous Waste Advisory Board. This Board shall review and recommend revisions to these procedures as appropriate.

Environmental Health and Safety shall be the University agency responsible for implementing and enforcing the established policy and procedure. This agency shall also be responsible for the coordination of all hazardous waste disposal efforts.

The Directors of Business Services, in conjunction with the individual hazardous waste generators at non-University Park locations, and the individual hazardous waste generators at University Park, shall be responsible for coordinating the collection of hazardous waste with Environmental Health and Safety.

The custody and disposition of all chemicals/materials obtained or produced by, for and/or resulting from experiments, research or purchase is the responsibility of the University employee and/of their organizational unit so pre-occupied. The organization's budget under which such chemicals/materials are obtained or produced may also be required to fund the analysis of such items which cannot be identified by their proper or generic name or are improperly labeled. All containers of chemicals/materials must be clearly identified and labeled as to their contents. UNKNOWN OR IMPROPERLY LABELED CHEMICALS/MATERIALS WILL NOT BE ACCEPTED FOR DISPOSAL.

Normal hazardous waste disposal costs will be funded through Environmental Health and Safety.

Generators of hazardous waste are responsible to ensure the appropriate storage, labeling, inspection, auditing, documentation, and segregation of chemicals, and to provide and document training of all personnel involved in the handling of this waste.

The indiscriminate drain-disposal of chemicals/materials is not permitted. Drain disposal of chemical waste materials shall be permitted only with specific written approval by Environmental Health and Safety.

Departments that generate hazardous chemical wastes shall ensure that a waste reduction program is in effect and that it is being adhered to.

#### **REDUCING HAZARDOUS MATERIALS:**

To effect a reduction in the volume of hazardous waste generated at the University, as mandated by the Pennsylvania Department of Environmental Protection (PA DEP), and the Environmental Protection Agency (EPA), generators of hazardous waste shall minimize the volume or toxicity of their waste.

- Substitutions can be made to eliminate or reduce the amount of hazardous ingredients.
- Management practices can greatly reduce unnecessary waste generation. This includes the purchase of only the quantity of material anticipated to be used and establishing usage parameters for each chemical.
- Hazardous materials may be redistributed or returned. Often, surplus chemicals can be redistributed within the University or returned to the manufacturer. Lists of redistributable chemicals should be circulated among faculty and staff within work units or departments. Such a list should contain the following information:
  - chemical name,
  - amount,
  - manufacturer,
  - Purity, as stated on label, and
  - whether the container is unopened.

EHS maintains a listing of chemicals that are available for redistribution.

- Bulking of compatible chemicals. Environmental Health and Safety shall provide guidance in the consolidation of compatible chemicals. A significant reduction in disposal costs can be achieved in the bulking of these chemicals.
- Waste segregation. Mixing wastes **can be** hazardous; incompatible wastes can react - and explode. Wastes transported to the Chemical Waste Storage facility must be segregated to avoid these reactions. A further

reduction in the costs for waste disposal can be achieved by reducing packaging time as compatible chemicals can be packed more efficiently. Chemicals should be segregated into the following categories: flammables, corrosives, poisons, and oxidizers.

- Integrate micro-scale techniques into organic and inorganic chemistry laboratory courses and research projects. These techniques can reduce chemical purchase costs and significantly reduce the quantities of waste chemicals for disposal. Use of micro-scale also reduces student and faculty exposure to toxic chemicals, carcinogens, flammables and explosives.

## RESPONSIBILITIES:

Individuals responsible for laboratories and other areas which handle and store hazardous waste are required to:

1. Each room generating chemical waste must designate a location within the room for waste accumulation. This area is referred to as the "Accumulation Area."
2. Designate an individual who is responsible to oversee the proper storage, labeling and inspection of this Accumulation Area and who conducts weekly inspections of this area, documenting and maintaining the results of the inspection.
3. Ensure all laboratory personnel involved in chemical waste management are trained and documentation of training records is maintained.
4. Establish, implement and document an annual review of all hazardous materials to ensure those exceeding safe and practical usage are properly disposed of.
5. Incorporate waste disposal management practices into all procedures, including laboratory manuals used for instruction.
6. Conduct audits of waste management procedures as established in this policy to ensure compliance and implement the necessary changes.

Department heads/heads of administrative units are responsible to:

1. Prepare a written program description for compliance with this policy and designate an individual responsible for department-wide compliance.
2. Maintain a listing of accumulation areas and individuals responsible for oversight.
3. Maintain copies of training documents.
4. Conduct audits of waste management procedures within facilities under their jurisdiction as established in this policy to ensure compliance and implement the necessary changes.

Deans of Academic Colleges/Heads of Administrative Units are responsible to:

1. Designate a College/Unit-wide individual to oversee program.
2. Conduct audits of waste management procedures established in this policy to ensure compliance and implement the necessary changes.

## PROCEDURES:

### Collection and transportation of hazardous waste at University Park:

A laboratory or facility that has hazardous waste for disposal shall contact Environmental Health and Safety, 6 Eisenhower Parking Deck, [www.ehs.psu.edu](http://www.ehs.psu.edu), Phone 865-6391 to obtain the necessary form (Chemical Waste Manifest Form), which must be properly completed for all requests for disposal of chemicals/materials. Environmental Health and Safety personnel will collect and transport the hazardous waste to the Chemical Accumulation Facility. Procedures for the collection of specially-arranged disposal activities will be established by EHS. The spill or discharge of any hazardous material must be reported to Environmental Health and Safety at 865-6391 during regular working hours (8:00 a.m. to 5:00 p.m.). At other times and on weekends, the incident must be reported to

University Police. Callers from 862, 863, and 865 telephones, dial 911; from other numbers, dial 863-1111. Environmental Health and Safety personnel will report to the site of the incident and provide guidance and direction in proper cleanup procedures, as deemed appropriate. They will provide or recommend appropriate equipment for the cleanup, and arrange for the proper disposal of the hazardous waste.

**Disposal of hazardous waste at non-University Park locations (except Hershey Medical Center):**

Other locations that have hazardous waste for disposal will forward a properly completed Chemical Waste Manifest Form to Environmental Health and Safety.

Environmental Health and Safety will arrange to have the hazardous waste picked up by a commercial vendor.

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Effective Date: November 9, 2000

Date Approved: November 7, 2000

Date Published: November 9, 2000 (editorial change - August 13, 2004)

**Most recent changes:**

- August 13, 2004 - (editorial change) Removed cross-reference to SYG01.
- November 9, 2000 - Policy updated to reflect changes in regulations, waste minimization and responsibilities.

**Revision History (and effective dates):**

- November 11, 1999 - EHS website address added and various minor editorial changes made.
- February 26, 1992
- April 26, 1988 - New Policy



## APPENDIX A 9

### UNIVERSITY FACULTY SENATE LEGISLATION

#### BACKGROUND:

In 1981, the University Faculty Senate passed legislation pursuant to the instructional duties of graduate teaching assistants (TAs). This legislation stated only the determination that TA preparation would satisfy two general requirements:

1. All international teaching assistants (ITAs) should take and pass a test of spoken English.
2. All teaching assistants, regardless of country of origin, should undergo some form of training or preparation for their instructional responsibilities.

Both these issues came to the fore only because of complaints from undergraduates—complaints that TAs could not be understood in class and that TAs in general were not providing quality instruction. Then, in 1991 and 1993, the University Faculty Senate passed more detailed legislation that mandated TA preparation and outlined more specifically how these two requirements would be met. At the heart of the senate legislation are the following six criteria of TA preparation:

1. All TAs must be provided the instructional goals and objectives for the course, and, if teaching in any capacity in front of the class, direction as to the content to be used to accomplish the goals and objectives.
2. TAs must be offered preparation in generic teaching strategies (e.g., how to question, how to respond to student comments, how to incorporate different types of explanations into lesson plans, how to construct and grade exams, etc.,
3. Departments must provide TAs with information on appropriate teaching methods, activities, exercises, and/or grading policies and techniques for the course to which the TA has been assigned.
4. Departments must provide all TAs with faculty supervision and/or mentorship.
5. All TAs must receive some type of formative instructional evaluation (i.e., evaluation that provides feedback about instructional effectiveness for the purpose of improving the TA's teaching).
6. Departments must direct international teaching assistants (ITAs) who score below 250 on the modified AEOCPT test (Penn State's American English Oral Communicative Proficiency test) to take the appropriate course (which constitute certification, required by Pennsylvania State Law) offered through the Program in English as a Second Language in the speech communication department and follow the guidelines for teaching responsibilities that correspond with the appropriate course.

