GRADUATE PROGRAM HANDBOOK

Department of Food Science

The Pennsylvania State University

Volume III

Department and University Policies

Academic Year 2015-2016

Department of Food Science
202 Erickson Food Science Building
The Pennsylvania State University
University Park, PA 16802

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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 Utlility (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 operating 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

Room Number	Faculty	Room Number	Faculty
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 Safey (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.

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 Erickson Food Science Building. 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

APPENDIX A 1
Administrative Policy AD47

GENERAL STANDARDS OF PROFESSIONAL ETHICS
http://guru.psu.edu/policies/AD47.html

Contents:

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 (See AD07). 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.

FURTHER INFORMATION:

For questions, additional detail, or to request changes to this policy, please contact the Office of the Executive Vice President and Provost.

CROSS REFERENCES:

Additional Policies to refer to would include:

AD07 - Use of University Name, Symbols and/or Graphic Devices,

HR35 - Public Service by Members of the Faculty and Staff,

HR91 - Conflict of Interest,

IP02 - Coauthorship of Scholarly Reports, Papers and Publications (Formerly RA13),

RP02 - Addressing Allegations of Research Misconduct (Formerly RA10, Handling Inquiries/Investigations Into Questions of Ethics in Research and in Other Scholarly Activities), and

RP03 - The Use of Human Participants in Research (Formerly Policy RA14).

Effective Date: May 10, 1996
Date Approved: June 10, 1996
Date Published: June 24, 1996 (Editorial change, August 21, 2014)

Most Recent Changes :

- August 21, 2014 - Editorial changes. In the STATEMENTS, VI. and CROSS REFERENCES sections, reference to Policy AD07, *Use of University Name, Symbols and/or Graphic Devices*, has been added. Addition of policy steward information, in the event that there are questions or requests for changes to the policy.

Revision History (and effective dates):

- June 14, 2006 - Revision History added.
- 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:

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 14 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:

Graduate assistants must be enrolled at Penn State as graduate students. More specifically, since assistantships are provided as aids to completion of advanced degrees, assistants are expected to enroll for credit loads each semester that fall within the limits indicated in the table below. Maximum limits on permissible credit loads are indicated in order to assure that the student can give appropriate

attention both to academic progress and assistantship responsibilities. These considerations give rise to the table of permissible credit loads below.

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 **be**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, 814-865-7467, or see "Graduate Assistant and Graduate Fellow Health Insurance Plan" on the University Health Services website.

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.

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 before 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	3-4

The credits specified are the number which the appointee is ordinarily expected to carry.To provide for some flexibility, moderate exceptions to the specified limits may be made in particular cases. The credit

limits specified above may only be increased or decreased in exceptional cases for a specific semester or summer session by permission of the assistantship supervisor, the student's academic adviser, and the dean of the Graduate School (requests should be submitted for the dean's approval via the Office of Graduate Enrollment Services). It is expected that:

- 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 he/she gains experience and skill enabling the individual to take responsibility. Each graduate assistant shall have his or her work evaluated at least once each year, and the supervisor shall discuss with the individual how well he/she performed during the appointment period.

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.

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.

FURTHER INFORMATION:

For questions, additional detail, or to request changes to this policy, please contact the Payroll Office.

Effective Date: March 29, 2012
Date Approved: March 27, 2012
Date Published: March 29, 2012 (Editorial changes, August 20, 2014)

Most Recent Changes:

- August 20, 2014 - Editorial changes. Clarifications in SUBMISSION OF FORMS FOR THE APPOINTMENT OF GRADUATE ASSISTANTS and PAYMENT OF STIPENDS sections to reflect current operations. Addition of policy steward information, in the event that there are questions or requests for changes to the policy.

Revision History (and effective dates):

- March 29, 2012 - Revisions have been made to the ELIGIBILITY and CREDITS THAT MAY BE SCHEDULED sections, clarifying details that pertain to these categories.
- September 19, 2011 - Editorial changes made to HEALTH INSURANCE BENEFITS, clarifying contact information, if futher information is needed.
- 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
- 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 incresed from 8-11 to 9-12.
- May 22, 2001 -
    - Under the RESPONSIBILITIES section, changed the advance approval requirements from "dean of the college where the student holds the assistantship" to "administrative head of the academic unit in which the assistantship is held, and of the chair of the student's graduate academic program."
- January 24, 2000 -
    - Mandatory direct deposit of pay.
    - Added link to Penn State Graduate Degree Programs Bulletin.
    - Changed term 'earned tuition grant-in-aid' to 'Tuition Assistance Program'.
    - Revised RESPONSIBILITIES section.
    - Changed 1/4 time fall/spring credits from 11-14 to 9-14
- December 3, 1996 - Removed references to several defunct forms (Loyalty Oath and Affirmation, and Alien Information Request); changed title "Senior Vice President for Research and Dean of the Graduate School" to "Dean of the Gradyate School."
- April 4, 1994 - IBIS ASST form reference replaced by NAPP, GFSA, GRAD,TRMN, and GFST.
- November 22, 1993 -

  - HEALTH INSURANCE BENEFIT section added.
  - Alien Information Request Form and Salary Deposit Request added as required forms to submit.
  - Effective November 1, 1993, direct salary deposits shall be mandatory and a condition of hire for anyone beginning employment on or after that date.
  - Provision added for salary advance for first monthly payroll.

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- October 1, 1993 - Added Intellectual Property Agreement as a required form to be completed by a graduate assistant.
- May 22, 1991 - The Assistantship and Fellowship Stipend Form raplaced by the IBIS ASST form: Under ELIGIBILITY, added provisions for candidiates to have health insurance.
- April 12, 1988 -
  - Added Employment Eligibility Verification Form (INS Form I-9) to FORMS TO BE COMPLETED section.
  - Removed section TUITION REMISSIONS EDUCATION ASSISTANCE PLAN.
  - At locations other than UP, references to the "Bursar" should be read as Financial (or Business) Office.
- March 27, 1987 - "Employee's Withholding Exemption Certificate" change to "Employee's Withholding Allowance Certificate"; added lengthy section TUITION REMISSIONS EDUCATION ASSISTANCE PLAN.
- April 18, 1985 -
  - Under section TYPES AND SALARY RANGES, "summer session 10 weeks (or extended session 12 weeks)" changed to " extended summer session 12 weeks."
  - "Dean of the Graduate School" changed to "Vice President for Research and Dean of the Graduate School."
  - Credits for 1/4, 1/2, and 3/4 time graduate assistants now identifed for fall or spring semester.
  - Credits for summer added as follows: 1/4 time = 5-7; 1/2 time = 4-6; 3/4 time = 3-5.
- July 25, 1983 -
  - Removed section PRIVILEGES FOR GRADUATE STUDY GRANT-IN-AID and replaced with section RATES TO CHARGE FUNDING
  - Provisions of new section include: tuition will be charged to sponsored agreements at an average in-state rate, effective summer session 1984; flat rate dissertation fees will be charge to sponsored agreements for assistantships effective fall semester 1983; earned tuition grant-in-aid will not be available after summer term, 1983.
  - "Business Manager" changed to "Director of Business Services."
- April 15, 1983 -
  - Term" changed to "Semester".
  - Budget Executive signs Assistant and Fellowship Stipend Form instead of dean or administrative officer.
  - 1/4 time Fraduate Assistant changed from 7-9 credits to 11-14 credits.
  - 1/2 time graduate Assistant changed from 5-7 credits to 8-11 credits.
  - 3/4 Time Graduate Assistant changed from 4-5 credits to 6-8 credits.
  - All graduate assistant appointees are paid monthly instead of 6 equal installments per term.
  - The total credit load over a period of time must conform with the specified limits.
  - Under section PRIVILEGES FOR GRADUATE STUDY GRANT-IN-AID, deleted the phrase " The additional grant-in-aid may not be accumulated."
  - Changed "application for Earned Extra Grant-In-Aid" to Application for Tuition Grant-In-Aid."
- June 1, 1981 - The Assistantship and Fellowship Stipend Form and Employee's Withholding Exemption Certificate are to be submitted to Financial Officer (and not to Budget Office); at Commonwealth Campuses references to the "Bursar" should be read as Financial (or Business)

Office. Reference to "Financial Officer" should be read as Business Manager if no Financial Officer is asigned to the Campus.

- April 17, 1978 - Added that submission of forms for appointment is required in Payroll Office one month before the first pay date each term.
- April 1, 1974 -
    - Added stipulation for same pay, same work within any department.
    - Significant reorganization of policy's sections including a new section RESPONSIBILITIES.
- July 1, 1968 - New Policy.

APPENDIX A 3

Policy RP02 - ADDRESSING ALLEGATIONS OF RESEARCH MISCONDUCT (Formerly *RA10*)

Policy Steward: Associate Vice President for Research, Director of the Office for Research Protections

Contents:

PURPOSE:

To establish policy and procedures to address allegations of research misconduct.

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:

Research misconduct is prohibited. Allegations of research misconduct shall be addressed in accordance with this policy and applicable regulations.

Faculty and staff members and students are required to comply with this policy and applicable regulations. Violation of this policy by a member of the faculty or staff, or a student, may subject the faculty or staff member or student to imposition of disciplinary sanctions, including, but not limited to, dismissal from employment or enrollment.

DEFINITION OF TERMS:

Research Misconduct is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results. It does not include honest error or differences of opinion.

Fabrication is defined as making up data or results and recording or reporting them.

Falsification is defined as manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Plagiarism is defined as the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Allegation is defined as any oral or written disclosure 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.

Research Integrity Officer means the Associate Vice President for Research and Director of the Office for Research Protections, who is the person appointed by the Vice President for Research to assume the responsibilities assigned to the Research Integrity Officer under this policy and applicable regulations.

GENERAL POLICY AND PRINCIPLES:

I. Responsibility to Report Possible Research Misconduct

Anyone having reason to believe that a member of the faculty, staff or student body has engaged in research misconduct has a responsibility to report pertinent facts in accordance with this policy. The person may discuss the situation with a Budget Administrator or Budget Executive or the Research Integrity Officer or may report the facts through other established reporting procedures, such as the University's ethics hotline. A Budget Administrator or Budget Executive who receives information about possible research misconduct shall inform the Research Integrity Officer. If the circumstances described do not meet the definition of research misconduct, the Research Integrity Officer may refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

II. Confidentiality

The Research Integrity Officer shall endeavor to protect the confidentiality of respondents and complainants, and of research subjects identifiable from research records or evidence, by

limiting disclosure to those who need to know in order to carry out a thorough, competent, objective, and fair research misconduct proceeding or as required by law.

III. Interim Administrative Actions and Notifying Federal Agencies of Special Circumstances

Throughout the research misconduct proceeding, the Research Integrity Officer will ensure that warranted interim actions are taken to protect public health, sponsor funds and equipment, and the integrity of the research process, and to ensure that the purposes of the research activity and the financial assistance are carried out. Such actions may include, for example, additional monitoring of the research process and the handling of federal funds and equipment, reassignment of personnel or of responsibility for handling federal funds and equipment, additional review of research data and results, and delay in publication.

To the extent required by regulation or by the sponsor, the Research Integrity Officer shall, at any time during a research misconduct proceeding, notify appropriate federal or other officials of facts that may be relevant to protect public health, federal or other sponsor funds and equipment, and the integrity of the sponsor-supported research process and shall make other interim reports required by research sponsors.[1]

[1] Regulations applicable to research misconduct allegations under U.S. Public Health Service ("PHS") jurisdiction require immediate notification of the PHS Office of Research Integrity ("ORI") if the University has reason to believe that any of the following conditions exist: (1) health or safety of the public is at risk, including an immediate need to protect human or animal subjects; (2) U.S. Department of Health and Human Services ("HHS") resources or interests are threatened; (3) research activities should be suspended; (4) there is a reasonable indication of possible violations of civil or criminal law; (5) federal action is required to protect the interests of those involved in the research misconduct proceeding; (6) the University believes the research misconduct proceeding may be made public prematurely (so that HHS may take appropriate steps to safeguard evidence and protect the rights of those involved); or (7) the research community or public should be informed. 42 C.F.R. 93.318. Regulations applicable to research misconduct allegations under National Science Foundation ("NSF") jurisdiction require prompt notification of the NSF Office of Inspector General ("NSF OIG") should the University become aware during an Inquiry or Investigation that: (1) Public health or safety is at risk; (2) NSF's resources, reputation, or other interests need protecting; (3) There is reasonable indication of possible violations of civil or criminal law; (4) Research activities should be suspended; (5) Federal action may be needed to protect the interests of a subject of the Investigation or of others potentially affected; or (6) The scientific community or the public should be informed. 45 C.F.R. 689.4(c).

PROCEDURE:

I. Conducting the Inquiry

A. Assessment of Allegations

As soon as practicable after receiving an allegation of research misconduct, the Research Integrity Officer will assess the allegation to determine whether it (1) falls within the definition of research misconduct in this Policy and any applicable federal regulations, and (2) is sufficiently credible and specific so that potential evidence of research misconduct may be identified. If both of these criteria are met, an Inquiry will be conducted unless the Research Integrity Officer determines that unusual circumstances exist that make an inquiry infeasible or otherwise not warranted (such as that the conduct at issue is too old; see 42 CFR 93.105).

B. Notice to Respondent

At the time of or before beginning an Inquiry, the Research Integrity Officer shall make a good faith effort to notify the respondent in writing of the decision to conduct an Inquiry. If the Inquiry subsequently identifies additional respondents, they shall also be notified in writing.

C. Sequestration of the Research Records

On or before the date on which the respondent is notified, or the Inquiry begins, whichever is earlier, the Research Integrity Officer shall take all reasonable and practical steps to obtain custody of all the research records and evidence needed to conduct the research misconduct proceeding, inventory the records and evidence, and sequester them in a secure manner. Where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies have evidentiary value substantially equivalent to that of the instruments.

D. Appointment of the Inquiry Committee

The Research Integrity Officer is responsible for conducting, or designating others to conduct, the Inquiry.[2] In cases where the allegations and apparent evidence are straightforward, the Research Integrity Officer may choose to conduct the Inquiry directly or designate another qualified individual, referred to as the inquiry official, to do so. The inquiry official shall not have unresolved personal, professional, or financial conflicts of interest in relation to the Inquiry and should have appropriate scientific expertise to evaluate the evidence and issues related to the allegation and conduct the Inquiry.

[2]Inquiry or Investigation that: (1) Public health or safety is at risk; (2) NSF's resources, reputation, or other interests need protecting; (3) There is reasonable indication of possible violations of civil or criminal law; (4) Research activities should be suspended; (5) Federal action may be needed to protect the interests of a subject of the Investigation or of others potentially affected; or (6) The scientific community or the public should be informed. 45 C.F.R. 689.4(c).

In complex cases, the Research Integrity Officer, in consultation with other University officials, as appropriate, will normally appoint a committee of three or more persons, including a committee chair, to conduct the Inquiry. Where warranted, the Research Integrity Officer may determine that a smaller or larger committee is appropriate. The members of the inquiry committee shall consist of individuals who do not have unresolved personal, professional, or financial conflicts of interest in relation to the Inquiry and should include individuals with the appropriate scientific expertise to evaluate the evidence and issues related to the allegation and conduct the Inquiry. When necessary to secure expertise or to avoid conflicts of interest, the Research Integrity Officer may select committee members from outside the University.

The Research Integrity Officer, in consultation with the inquiry committee, will determine whether additional experts are needed to provide special expertise to the inquiry committee regarding the analysis of specific evidence. If experts are utilized, their role will be advisory to the inquiry committee.

The respondent shall have an opportunity to object to the inquiry official or a proposed member of the inquiry committee based upon a personal, professional, or financial conflict of interest, by submitting written objections to the Research Integrity Officer no more than 10 days following notification of the proposed inquiry official or committee

membership. The Research Integrity Officer makes the final determination as to whether a conflict exists.

E. Charge to the Inquiry Committee

The Research Integrity Officer will prepare a charge to the inquiry official or inquiry committee that: (1) sets forth the time for completion of the Inquiry; (2) describes the allegations and any related issues identified during the allegation assessment; (3) states that the purpose of the Inquiry is to conduct an initial review of the evidence to determine whether an Investigation is warranted, not to determine whether research misconduct definitely occurred or who was responsible; (4) states the criteria for determining that an Investigation is warranted; and (5) states that the inquiry official or inquiry committee is responsible for preparing or directing the preparation of a written report of the Inquiry that meets the requirements of Section V of this Policy.

The Research Integrity Officer may choose to meet with the inquiry official or inquiry committee to review the charge, discuss the allegations, discuss the appropriate procedures for conducting the Inquiry, assist the inquiry official or committee with organizing plans for the Inquiry, and answer any questions raised by the inquiry official or committee. The Research Integrity Officer or his or her designee will be available throughout the Inquiry to advise the inquiry official or inquiry committee as needed.

F. Inquiry Process

The purpose of the Inquiry is to conduct an initial review of the available evidence to determine whether to conduct an Investigation. The purpose of the Inquiry is not to decide whether research misconduct definitely occurred, determine who committed the research misconduct or conduct exhaustive interviews and analysis. If interviews are conducted as part of the Inquiry, each interview shall be recorded or transcribed, and the recording or transcript shall be provided to the interviewee for correction and shall be included, with any written corrections, in the record of the Inquiry.

After evaluation of the evidence, the inquiry official or inquiry committee will consult with the Research Integrity Officer and decide whether to recommend that an Investigation is warranted. An Investigation is warranted if: (1) there is a reasonable basis for concluding that the allegation falls within the definition of research misconduct in this Policy and (2) preliminary information-gathering and preliminary fact-finding from the Inquiry indicate that the allegation may have substance.

If the respondent admits research misconduct, a determination of misconduct may be made at or before the Inquiry stage if all relevant issues are resolved. In that case, the Research Integrity Officer, in consultation with the Vice President for Research and other appropriate University officials, shall promptly consult with any appropriate federal agencies to determine the next steps that should be taken.

G. Time for Completion

The Inquiry, including preparation of the final inquiry report and the decision of the Vice President for Research on whether an Investigation is warranted, must be completed within 60 days of its initiation unless the Research Integrity Officer determines that circumstances warrant a longer period. If the Inquiry takes longer than 60 days, and the Research Integrity Officer approves an extension, the Inquiry record shall include documentation of the reasons for exceeding the 60-day period.

II. The Inquiry Report

. Elements of the Inquiry Report

A written inquiry report shall be prepared that includes the following information: (1) the name and position of the respondent; (2) a description of the allegations of research misconduct; (3) pertinent federal agency support, including, for example, grant numbers, grant applications, contracts, and publications listing such support; (4) the basis for recommending or not recommending that the allegations warrant an Investigation; and (5) any written comments on the draft report by the respondent or the complainant.

The inquiry report should also include: the names and titles of the inquiry official or committee members and experts who conducted the Inquiry; a summary of the inquiry process used; a list of the research records reviewed; and whether any other actions should be taken if an Investigation is not recommended. The inquiry report shall either be signed by the inquiry official or by each member of the inquiry committee or shall include other written evidence of each person's concurrence or non-concurrence with the findings and conclusions of the Inquiry.

A. Opportunity to Comment on the Inquiry Report

The Research Integrity Officer shall provide the respondent with a copy of the draft inquiry report and, concurrently, with a copy of any applicable federal research misconduct policy. The respondent shall be provided with an opportunity to review and comment on the inquiry report. Any comments from the respondent must be in writing and received within 10 days of his/her receipt of the inquiry report and will be attached to the report. Based on the comments, the inquiry committee may revise the draft report as appropriate and prepare it in final form. The Research Integrity Officer will deliver the final report to the Vice President for Research.

The Research Integrity Officer may provide the complainant with relevant portions of the inquiry report for comment. Any comments from the complainant must be in writing and received within 10 days of his/her receipt of the inquiry report.

B. Decision and Notification

1. Decision by the Vice President for Research

   The Research Integrity Officer will transmit the final inquiry report and any written comments to the Vice President for Research, who will determine in writing whether an Investigation is warranted. The Inquiry is complete when the Vice President for Research makes this determination.

2. Notice to Respondent and Complainant

   The Research Integrity Officer shall notify the respondent whether the Inquiry found that an Investigation is warranted. The notice shall include a copy of the inquiry report and include a copy of or refer to this Policy and any applicable federal research misconduct policy.

3. Notice to Applicable Sponsor or Federal Agency

   The Research Integrity Officer shall provide to applicable sponsors or federal agencies any required reports regarding the Inquiry and decision to initiate an Investigation. For cases involving ORI jurisdiction, within 30 days of the Vice President for Research's decision that an Investigation is warranted, but not later

than the date the Investigation begins, the Research Integrity Officer shall provide ORI with the Vice President for Research's written decision and a copy of the inquiry report. The Research Integrity Officer will also notify University officials who need to know of the Vice President for Research's decision.

4. Documentation of Decision Not to Investigate

If the Vice President for Research decides that an Investigation is not warranted, the Research Integrity Officer shall secure and maintain, for seven years after the termination of the Inquiry, sufficiently detailed documentation of the Inquiry to permit a later assessment by supporting federal agencies of the reasons why an Investigation was not conducted. These documents shall be provided to authorized federal personnel upon request.

III. Conducting the Investigation

Initiation and Purpose

The Investigation shall begin within 30 days after the Vice President for Research's determination that an Investigation is warranted. The purpose of the Investigation is to develop a factual record by exploring the allegations in detail and examining the evidence in depth, leading to findings on whether research misconduct has been committed, by whom, and to what extent. The Investigation will also determine whether there are additional instances of possible research misconduct that would justify broadening the scope beyond the initial allegations. The findings of the Investigation shall be set forth in an investigation report.

. Notice to Respondent

Within a reasonable time after determining that an Investigation is warranted, but before the Investigation begins, the Research Integrity Officer shall notify the respondent in writing of the allegations to be investigated. If allegations not addressed during the Inquiry or in the initial notice of the Investigation are pursued, the Research Integrity Officer shall give the respondent written notice of any such new allegations.

A. Sequestration of the Research Records

Before or at the time the University notifies the respondent of the Investigation, the Research Integrity Officer shall take all reasonable and practical steps to obtain custody of and sequester in a secure manner all research records and evidence needed to conduct the research misconduct proceeding that were not previously sequestered during the Inquiry. Where the research records or evidence encompass scientific instruments shared by a number of users, custody may be limited to copies of the data or evidence on such instruments, so long as those copies are substantially equivalent, in evidentiary value, to the instruments. If additional items become known or relevant during the Investigation, the Research Integrity Officer shall take reasonable and practical steps to obtain custody of those records.

B. Appointment of the Investigation Committee

As soon as practicable after the Vice President for Research determines that an Investigation is warranted, the Research Integrity Officer, in consultation with other University officials, as appropriate, will appoint an investigation committee and committee chair, which will conduct the Investigation.

The investigation committee shall consist of individuals who did not serve on the inquiry committee and who do not have unresolved personal, professional, or financial conflicts of interest in relation to the Investigation. Investigation committee members should have appropriate scientific expertise to evaluate the evidence and issues related to the allegation, interview the respondent and complainant, and conduct the Investigation. When necessary to secure expertise or to avoid conflicts of interest, the Research Integrity Officer may select committee members from outside the University. The Research Integrity Officer may not serve as a member of the investigation committee.

The respondent shall have an opportunity to object to proposed members of the investigation committee based upon personal, professional or financial conflict of interest, by submitting written objections to the Research Integrity Officer no more than 10 days following notification regarding the committee membership. The Research Integrity Officer makes the final determination as to whether a conflict exists.

C. Charge to the Investigation Committee

The Research Integrity Officer will define the subject matter of the Investigation in a written charge to the investigation committee that: (1) describes the allegations and related issues identified during the Inquiry; (2) identifies the respondent; (3) informs the investigation committee that it must conduct the Investigation as prescribed in this Policy; (4) defines research misconduct; (5) informs the investigation committee that it must evaluate the evidence and testimony to determine whether, based on a preponderance of the evidence, research misconduct occurred and, if so, the type and extent and who was responsible; and (6) informs the investigation committee that it must prepare or direct the preparation of a written investigation report that meets the requirements of Section VII.A.

The Research Integrity Officer may choose to meet with the investigation committee to review the charge, the inquiry report, and prescribed procedures and standards for the conduct of the Investigation, including the necessity for confidentiality and for developing a specific Investigation plan.

The investigation committee shall be provided with a copy of this Policy and any applicable federal research misconduct policy. The Research Integrity Officer or designee will ordinarily be available throughout the Investigation to advise the investigation committee as needed.

D. Investigation Process

The investigation committee and the Research Integrity Officer shall:

1. Use diligent efforts to ensure that the Investigation is thorough and sufficiently documented and includes examination of all research records and evidence relevant to reaching a decision on the merits of each allegation;
2. Take reasonable steps to ensure an impartial and unbiased Investigation to the maximum extent practical, including participation of persons with appropriate scientific expertise who do not have unresolved personal, professional, or financial conflicts of interest with those involved with the Inquiry or Investigation;
3. Interview each respondent, complainant, and any other available person who has been reasonably identified as having information regarding any relevant aspects of the Investigation, including witnesses identified by the respondent, and record and transcribe each interview, provide the recording or transcript to the interviewee for correction, and include the recording or transcript, and any written corrections, in the record of the Investigation; and

4. Pursue diligently all significant issues and leads discovered that are determined relevant to the Investigation, including any evidence of additional instances of possible research misconduct, and continue the Investigation to completion.

E. Standard for Making a Finding of Research Misconduct

In order to make a finding of research misconduct, the investigation committee must find by a preponderance of the evidence that: (1) research misconduct occurred, as defined in this Policy or applicable federal agency policy; (2) the research misconduct is a significant departure from accepted practices of the relevant research community; and (3) the respondent committed the research misconduct intentionally, knowingly, or recklessly.

The Research Integrity Officer will advise the investigation committee of any additional applicable regulatory standards for making a finding of research misconduct. (*See, for example*, 42 CFR 93.106.)

F. Time for Completion

The Investigation shall ordinarily be completed within 120 days of its initiation, including conducting the Investigation, preparing the report of findings, providing the draft report for comment, and sending the final report to any applicable federal agency. However, if the Research Integrity Officer determines that the Investigation will not be completed within the 120-day period, or as requested by the applicable agency, he/she shall submit to the applicable agency, or if no agency is involved, to the Vice President for Research, a written request for an extension setting forth the reasons for the delay.

IV. The Investigation Report

. Elements of the Investigation Report

The investigation committee and the Research Integrity Officer are responsible for preparing a written investigation report which shall: (1) describe the nature of the allegation of research misconduct; (2) describe and document any federal or private funding, including, for example, any grant numbers, grant applications, contracts, and publications listing any such support; (3) describe the specific allegations of research misconduct considered in the Investigation; (4) include a copy of this Policy; and (5) identify and summarize the research records and evidence reviewed and identify any evidence taken into custody but not reviewed.

The report shall also include a statement of findings for each separate allegation of research misconduct identified during the Investigation. Each statement of findings shall provide a decision as to whether misconduct did or did not occur, and if so --

(1) Identify whether the research misconduct was:

a. falsification, fabrication, or plagiarism,
b. a significant departure from accepted practices of the relevant research community, and
c. committed intentionally, knowingly, or recklessly;

(2) Summarize the facts and the analysis that support the conclusion and consider the merits of any reasonable explanation by the respondent;

(3) Identify specifically any pertinent federal support or proposals (reports to ORI shall include current support from, and known applications or proposals for support to, PHS as well as other federal agencies);

(4) Identify whether publications need correction or retraction; and

(5) Identify the person(s) responsible for the misconduct.

The investigation report shall either be signed by each member of the investigation committee or shall include other written evidence of each member's concurrence or non-concurrence with the findings and conclusions of the Investigation.

A. Comments on the Draft Investigation Report and Access to Evidence

0. Respondent

The Research Integrity Officer shall provide the respondent with a copy of the draft investigation report for comment, and shall provide the respondent, concurrently, with a copy of, or supervised access to, the evidence on which the report is based. The respondent shall be allowed 30 days to review the draft report and submit written comments to the Research Integrity Officer. The respondent's comments shall be taken into consideration when preparing the final investigation report and shall be attached to the final report.

1. Complainant

The Research Integrity Officer may provide the complainant with a copy of the draft investigation report, or relevant portions of it, for comment. If provided with a copy of the report, the complainant's comments must be in writing and submitted within 30 days of the date on which he/she received the draft report. Comments received from the complainant shall be taken into consideration in preparing the final investigation report and shall be attached to the final report.

2. Confidentiality

In distributing the draft report, or portions thereof, to the respondent or complainant, the Research Integrity Officer will inform the recipient of the confidentiality under which the draft report is made available and may establish reasonable conditions to ensure such confidentiality. For example, the Research Integrity Officer may require that the recipient sign a confidentiality agreement.

B. Decision by the Vice President for Research

The Research Integrity Officer will assist the investigation committee in finalizing the draft investigation report, including ensuring that the respondent's and, in appropriate cases, the complainant's written comments are included and considered. The Research Integrity Officer will transmit the final investigation report to the Vice President for Research, who will determine in writing: (1) whether the University accepts the Investigation's findings; and (2) the appropriate internal actions to be taken or recommended in response to the accepted findings of research misconduct. If the Vice President for Research's determination varies from the findings of the investigation committee, the Vice President for Research will, as part of his/her written determination, explain in detail the basis for rendering a decision different from the findings of the investigation committee. Alternatively, the Vice President for Research may return the report to the investigation committee with a request for further fact-finding or analysis.

When a final decision on the case has been reached, the Research Integrity Officer will normally notify both the respondent and the complainant in writing. The Research Integrity Officer is also responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies. The Vice President for Research in consultation as appropriate with the Research Integrity Officer and other University officials will determine whether law enforcement agencies, professional societies, professional licensing boards, editors of journals in which falsified reports may have been published, collaborators of the respondent in the work, or other relevant parties should be notified of the outcome of the case.

C. Notice to Applicable Federal Agencies of University Findings and Actions

Unless an extension has been granted, within 120 days of beginning the Investigation, the Research Integrity Officer shall submit to any applicable federal agency a copy of the final investigation report with attachments; a statement of whether the University accepts the findings of the investigation report; a statement of whether the University found research misconduct and, if so, who committed the misconduct; and, if required by the agency, a description of any pending or completed administrative actions against the respondent.

D. Maintaining Records for Review by Federal Agencies

The Research Integrity Officer shall maintain, and upon request, provide to authorized federal officials, records of the research misconduct proceedings, including: (1) records secured by the University for the Inquiry and Investigation; (2) documentation of the determination of irrelevant or duplicate records; (3) the inquiry report and final documents produced in the course of preparing that report, including the documentation of any decision not to investigate; and (4) the investigation report and the records in support of that report, including the recording or transcript of each interview conducted pursuant to this Policy.

Unless custody has been transferred to the applicable federal agency or the agency has advised the University, in writing, that the records no longer need to be retained, these records shall be maintained in a secure manner for seven years after the later of completion of the proceeding or the completion of any federal agency proceeding involving the research misconduct allegation.

The Research Integrity Officer is also responsible for providing any information, documentation, research records, evidence, or clarification requested by authorized federal officials to carry out their review of an allegation of research misconduct or of the University's handling of such an allegation.

V. Completion of Cases and Reporting Premature Closures to Applicable Federal Agencies

Generally, all Inquiries and Investigations will be carried through to completion and all significant issues will be pursued diligently. The Research Integrity Officer shall, if required by such agency, notify any applicable federal agency in advance if there are plans to close a case at the Inquiry or Investigation stage on the basis that the respondent has admitted guilt, a settlement with the respondent has been reached, or for any other reason except that: (1) no notification to federal agencies need be provided when a case is closed after an Inquiry that finds pursuant to Section IV.F that an Investigation is not warranted; and (2) if an Investigation is completed, the University's findings must be reported as specified under Section VII.D of this Policy.

VI. Internal Administrative Actions

If the Vice President for Research determines that a finding of research misconduct is substantiated, the University, through the Vice President for Research, the Budget Executive,

the Budget Administrator or other appropriate official, may adopt sanctions, which may include, for example:

. Re-training;
   a. Unannounced or announced audits;
   b. A letter of reprimand or admonishment to be included in respondent's file;
   c. Supervision or monitoring of future work, including a requirement for certification by senior personnel that a person's work met specified conditions;
   d. Removal from the research project in question;
   e. Formal notification of sponsoring agencies, funding sources, co-authors, co-investigators, collaborators or journal editors;
   f. Withdrawal or correction of pending abstracts and papers emanating from the research where research misconduct was found;
   g. Formal withdrawal of pending applications for research support;
   h. Public announcements; and/or
   i. Restitution of funds.

If the Vice President for Research determines that a finding of research misconduct is substantiated, the Vice President for Research may also recommend to the Budget Executive or other appropriate University official, disciplinary sanctions, which may include, for example:

j. Probation or suspension;
   k. Initiation of steps leading to possible impact on salary; and/or
   l. Initiation of steps leading to possible termination of employment.

None of these sanctions limits the authority of the funding sponsor to impose its own sanctions.

VII. Other Considerations

. Protecting the Respondent

Respondents may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice. During research misconduct proceedings, the respondent may be accompanied by counsel or a personal adviser at interviews and meetings, but the lawyer or personal adviser's role will be limited to counseling the respondent, and the respondent will be responsible for answering all questions.

As requested and appropriate, the Research Integrity Officer and other University officials shall make all reasonable and practical efforts to protect or restore the reputation of persons alleged to have engaged in research misconduct but against whom no finding of research misconduct is made. Depending on the particular circumstances and the views of the respondent, the Research Integrity Officer should consider whether to notify those individuals aware of or involved in the research misconduct proceeding of the final outcome, publicize the final outcome in any forum in which the allegation of research misconduct was previously publicized, and/or expunge references to the research misconduct allegation from the respondent's personnel file.

A. Protecting the Complainant, Witnesses and Committee Members

University faculty, staff, and students may not retaliate in any way against complainants, witnesses, or committee members. Faculty, staff, and students should immediately

report any alleged or apparent retaliation against complainants, witnesses, or committee members to the Research Integrity Officer.

During the research misconduct proceeding and upon its completion, regardless of whether or not the University or a federal agency determines that research misconduct occurred, the Research Integrity Officer shall undertake all reasonable and practical efforts to protect the position and reputation of, or to counter potential or actual retaliation against, any complainant who made allegations of research misconduct in good faith and of any witnesses and committee members who cooperate in good faith with the research misconduct proceeding.

B. Allegations Not Made in Good Faith

If relevant, the Vice President for Research will determine whether the complainant's allegations of research misconduct were made in good faith, or whether a witness or committee member acted in good faith. If the Vice President for Research determines that the complainant knowingly made a false allegation of research misconduct, the Vice President for Research shall determine whether any administrative action will be taken against the complainant or whether any disciplinary action against the complainant will be recommended to the Budget Executive or other appropriate University official.

FURTHER INFORMATION:

For questions, additional detail, or to request changes to this policy, please contact the Office of the Associate Vice President for Research, Director of the Office for Research Protections.

CROSS-REFERENCES:

Other Policies should also be referenced, especially the following:

AD47 - General Standards of Professional Ethics

IP01 - Ownership and Management of Intellectual Property

RA12 - Technology Transfer and Entrepreneurial Activity (Faculty Research)

RP03 - The Use of Human Participants in Research (Formerly RA14)

Effective Date: June 8, 2015
Date Approved: June 4, 2015
Date Published: June 8, 2015

Most Recent Changes:

- June 8, 2015 - This policy was previously a Research Administration policy, RA10. It has been moved from the Research Administration section to the Research Protections section to reflect the reorganization, and links/cross references have been edited as appropriate.

Revision History (and effective dates):

- January 26, 2015- Editorial change to the DEFINITION OF TERMS section, clarifying the definition for the *Research Integrity Officer* (addition of the Associate Vice President for Research and Director of the Office for Research Protections to the definition).

- August 13, 2013- Major revisions to the entire policy.
- 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 Excutive and Budget Administrator references, where necessary. Updated links and other policy titles throughout the policy.
- 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

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 publication 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.

FURTHER INFORMATION:

For questions, additional detail, or to request changes to this policy, please contact the Office of the Vice President for Research and Dean of the Graduate School.

CROSS REFERENCES:

Other policies may also be referenced, especially the following:

AD47 - General Standards of Professional Ethics.

Effective Date: January 7, 2013
Date Approved: September 14, 2012
Date Published: January 7, 2013 (Editorial changes- December 20, 2013)

Most Recent Changes:

- December 20, 2013 - Editorial change in CROSS REFERENCES section. RA10, *Addressing Allegations of Research Misconduct*, has been removed. Revisions to RA10 make it no longer applicable to this particular IP policy as a cross reference.

Revision History (and effective dates):

- October 25, 2013 - Editorial changes. Addition of policy steward information, in the event that there are questions or requests for changes to the policy.
- January 7, 2013- Policy moved from the Research Administration (RA13) section to the new Intellectual Property section (IP02). Same name and verbiage was retained.
- February 25, 2010 - Minor editorial changes made throughout the policy.
- 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

Policy RP03 THE USE OF HUMAN PARTICIPANTS IN RESEARCH (Formerly Policy RA14)

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

Contents:

PURPOSE:

The Pennsylvania State University (University) 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. The University 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 the University's standards for the protection of human participants of research.

POLICY:

The University'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.html). 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.html)and

- Title 21 CFR 50, 56, 312, 600 and 812 of the Food and Drug Administration (FDA) (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm)

The University'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 University colleges and campus locations, with the exception of the College of Medicine (COM), which maintains a separate Assurance with OHRP. The Pennsylvania College of Technology is excepted from both of these assurances. These Assurances set forth the policies for the protection of human participants, and include the duties and procedures of the IRBs.

University-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 the University 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 University 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.html#46.102).

“**Human participant” or "Human subject"** 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.html#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 reasonable 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 reasonable 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” or "Human subject"** 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.html#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 the University includes both biomedical research and social science research. Due to the large volume and diverse nature of research conducted at the University, 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 Associate Vice President for Research (located at University Park campus) or the Vice Dean for Research and Graduate Studies, Penn State COM (located at COM) to recommend and implement policies and regulations for the protection of human participants in research.

1. The University has established two IRBs located at the University Park Campus. These IRBs review all of the research conducted by investigators from all University colleges and campus locations except the COM and the Pennsylvania College of Technology.
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, the University Park Regional Campus, and the Penn State Hershey Medical Group locations. 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 subject research in which the University is engaged (HRP-311 Engagement Determination), regardless of funding or research site, including the categories exempted or waived by OHRP or FDA regulations.

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 and approve research conducted outside the United States of America by the University 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) Committee Review, (2) Expedited Review, and (3) Exempt Review. Each type of review is specifically defined in the Federal regulations. The University IRBs must follow these specifications for designating the review type to remain in compliance with the Assurances.

Committee 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, a protocol, informed consent/assent form(s) (if applicable), and supporting documents (e.g., 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 Committee 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 HRP-024 – SOP- New Information, , HRP-001 – Standard Operating Procedure: Definitions, HRP-103 – Investigator Manual, Appendix A-1);
- 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.

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.html#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, a protocol, informed consent/assent form(s) (if applicable), and supporting documents (e.g., 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 HRP-024- Standard Operating Procedure: New Information, HRP-001 – Standard Operating Procedure: Definitions, HRP-103 – Investigator Manual, Appendix A-1);
- 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.

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.html#46.101). At the University, 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 an application, a protocol, informed consent form(s), if applicable, and supporting documents (e.g., recruitment materials, questionnaires/surveys, and grant proposals, [if applicable]). For information on modifications that are required to be submitted at the exempt level, refer to HRP-103 – Investigator Manual.

Activities that do not meet the definition of human subject research do not require review and approval by one of the Organization's IRBs and do not need to be submitted to one of the Organization's IRBs unless there is a question regarding whether the activity is human subject research. Any questions about whether an activity meets the regulatory definitions of human subject research should be referred to the IRB Office who will provide a determination.

OTHER INSTITUTIONS:

The IRB interacts with other institutions to ensure that IRB policies and procedures are followed when the University or PSHMC employees and students perform research at other institutions, or when personnel or students from other institutions perform research at the University 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 University 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 University 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 the University and human participants, arrangements for medical care for research-related injury, and monetary 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, 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 the University 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 University Policy RP06-*Disclosure and Management of Significant Financial Interests* (formerly Policy RA20), all investigators (as defined in RP06) must apprise the IRB of any significant financial interest. The term "Significant Financial Interest" and financial disclosure thresholds and other policy requirements are detailed and defined in Policy RP06. Additional requirements for researchers at Penn State Hershey campus can be located on the Penn State Hershey Conflict of Interest office website (http://www.pennstatehershey.org/web/administration/home/conflict). 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.

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 University 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 HRP-024 – Standard Operating Procedure: New Information, HRP-001 – Standard Operating Procedure: Definitions, HRP-103 – Investigator Manual, Appendix A-1)" and;

o Any suspected non-compliance as described in HRP-024 – Standard Operating Procedure: New Information, HRP-001 – Standard Operating Procedure: Definitions, HRP-103 – Investigator Manual, Appendix A-1); 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
205 The 330 Building
Innovation Park
University Park, PA 16802
(814) 865-1775

OR

Human Subjects Protection Office
Penn State University COM
90 Hope Drive, P.O. Box 855
Mail Code A115, Box 855
Hershey, PA 17033-0850
(717) 531-5687

This policy is reviewed and approved by the Associate Vice President for Research, Director of the Office for Research Protections.

FURTHER INFORMATION:

For questions, additional detail, or to request changes to this policy, please contact the Office of the Associate Vice President for Research, Director of the Office for Research Protections.

CROSS REFERENCES:

ADG08 - Collection, Storage and Authorized Use of Social Security Numbers and Penn State Identification Numbers (Replaced Policy AD19)

AD47 - General Standards of Professional Ethics

AD83 - Institutional Financial Conflict of Interest

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

RA16– Administration of Sponsored Project Contract and Subcontracts of the University

RP02 - Addressing Allegations of Research Misconduct (Formerly RA10, Handling Inquiries/Investigations Into Questions of Ethics in Research and in Other Scholarly Activities)

RP05 - Research Quality in Human Participant Research

RP06 - Disclosure and Management of Significant Financial Interests (formerly RA20, Individual Conflict of Interest)

RPG01 - The Responsible Conduct of Research

Procedure CR2078, Payment to Research Participants

Effective Date: June 8, 2015
Date Approved: June 4, 2015
Date Published: June 8, 2015

Most recent changes:

- June 8, 2015 - This policy was previously a Research Administration policy, RA14. It has been moved from the Research Administration section to the Research Protections section to reflect the reorganization, and links/cross references have been edited as appropriate.

Revision History (and effective dates):

- April 17, 2014
    - Editorial change from “PSU” to “University” throughout, revisions made in all sections of the policy to provide clarification and detail about changes in process, definitions, and reference documents.
    - Associate Vice President for Health Sciences research title changed to Vice Dean for Research and Graduate Studies, Penn State COM. Narrowed Authority of IRB section to only research in which the University is determined by the IRB to be engaged, deleted Cross Reference HRP-091. Added Penn State College of Medicine University Park Regional Campus to Applicability section, “human subject” and “human participant” defined to be used interchangeably in this policy, revised information regarding determination of non-human, non-research in Types of Review section.
- September 10, 2013 - Editorial change in CROSS REFERENCES section; replaced reference to Policy RA21 - *Institutional Financial Conflict of Interest Involving Sponsored Projects, Dedicated Gifts, Research, Scholarship, and Technology Transfer* (obsoleted) with Policy AD83- *Institutional Financial Conflict of Interest*.
- 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*."
- 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:

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

FURTHER INFORMATION:

For questions, additional detail, or to request changes to this policy, please contact the Office of the Associate Vice President for Research, Director of the Office for Research Protections.

CROSS REFERENCES:

Other Policies should also be referenced, especially:

SY20 - Hazardous Waste Disposal, and

SY24 - Use of Biohazardous Materials in Research and Instruction.

Effective Date: June 8, 2015
Date Approved: June 4, 2015
Date Published: June 8, 2015

Most recent changes:

- June 8, 2015 - This policy was previously a Research Administration policy, RA15. It has been moved from the Research Administration section to the Research Protections section to reflect the reorganization, and links/cross references have been edited as appropriate.

Revision History (and effective dates):

- August 12, 2010 - Editorial changes made; updated address and website links were revised in the POLICY and SUBMISSION PROCEDURE sections, respectively.
- 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://guru.psu.edu/policies/SY24.html

Contents:

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 42CRF73, 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 patechial 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 (Zymonema) 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

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:

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

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. UNKNOWNS 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 with in 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. Maintain a listing of accumulation areas and individuals responsible for oversight.

2. Maintain copies of training documents.

3. 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 complete a Chemical Waste Pickup Request Form available at www.ehs.psu.edu, or contact EHS at 814-865-6391.
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 (Monday-Friday, 8:00 a.m. to 5:00 p.m.). At other times and on weekends, the incident must be reported to University Police and Public Safety at 814-863-1111. 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 Pickup Request Form to Environmental Health and Safety.

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

FURTHER INFORMATION:

For questions, additional detail, or to request changes to this policy, please contact the Director of Environmental Health and Safety.

Effective Date: November 9, 2000
Date Approved: November 7, 2000
Date Published: November 9, 2000 (Editorial changes, June 16, 2014)

Most recent changes:

- June 16, 2014- Corrections to Revision History, August 4, 1976 through February 26, 1992, per additional information discovered and added to the working papers.

- June 12, 2014 - Policy updated to reflect minor operational and editorial changes in POLICY, RESPONSIBILITIES and PROCEDURES sections. Added policy steward/ further information references, in the event that there are questions or requests for changes to the policy.

Revision History (and effective dates):

- August 13, 2004 - (editorial change) Removed cross-reference to SYG01.
- November 9, 2000 - Policy updated to reflect changes in regulations, waste minimization and responsibilities.
- November 11, 1999 - EHS website address added and various minor editorial changes made.
- February 26, 1992- Updates to POLICY, REDUCING HAZARDOUS MATERIALS and PROCEDURES sections to clarify current requirements.
- April 26, 1988 - Policy organized into standard Penn State policy categories. Edits made to REDUCING HAZARDOUS MATERIALS and PROCEDURES sections.
- August 4, 1976 - Earliest record of Original Policy, provided from EHS files and placed in S&P working papers.

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.