Stevenson University

Policy Manual

Volume IV

FACULTY POLICIES

May 8, 2015

Table of Contents

Volume IV

FACULTY POLICIES

4.1 GENERAL STATEMENT

Volume IV of the Stevenson University Policy Manual contains policies that pertain to members of the University faculty. Additional policies pertaining to all employees are provided in Volume III. Governance policies including the Constitution and Bylaws of the Faculty Council are provided in Volume I. General policies that affect all members of the campus community (including students) are set forth in Volume II. Volume V Student Policy Manual contains academic policies such as academic integrity policies and the grade appeal policy, conduct policies, sexual misconduct policies, and other policies.

4.2 ORGANIZATION OF ACADEMIC SCHOOLS

BROWN SCHOOL OF BUSINESS AND LEADERSHIP

1. **Program in Accounting**
    - Accounting
2. **Department of Business Administration**
    - Business Administration
    - Digital Marketing
    - Fashion Merchandising
3. **Department of Information Systems**
    - Business Information Systems
    - Computer Information Systems
4. **Program in Paralegal Studies**
    - Paralegal Studies

SCHOOL OF DESIGN

1. **Department of Art**
    - Visual Communication Design
2. **Department of Business Communication**
    - Business Communication
3. **Program in Fashion Design**
    - Fashion Design
4. **Program in Film and Moving Image**
    - Film and Moving Image

SCHOOL OF EDUCATION

1. **Early Childhood Education: Liberal Arts and Technology**
2. **Elementary Education: Liberal Arts and Technology**
3. **Middle School: Liberal Arts and Technology**

SCHOOL OF GRADUATE AND PROFESSIONAL STUDIES

Accelerated Bachelor's Degree Programs

1. **Program in Business Administration**
    - Business Administration
2. **Program in Business Communication**
    - Business Communication
3. **Program in Business Information Systems**
    - Business Information Systems
4. **Program in Computer Information Systems**
    - Computer Information Systems

5. **Program in Criminal Justice**
    - Criminal Justice
6. **Program in Interdisciplinary Studies**
    - Interdisciplinary Studies
7. **Program in Paralegal Studies**
    - Paralegal Studies
8. **Program in Nursing**
    - Nursing: RN to BS Option
    - Nursing: RN to MS Option

Master's Degree Programs

1. **Program in Business and Technology Management**
    - Business and Technology Management
2. **Program in Cyber Forensics**
    - Cyber Forensics
3. **Program in Forensic Sciences**
    - Forensic Sciences
4. **Program in Forensic Studies**
    - Forensic Studies
5. **Program in Healthcare Management**
    - Healthcare Management
6. **Program in Masters of Arts in Teaching**
    - Masters of Arts in Teaching: Biology, Chemistry, Mathematics
7. **Program in Nursing**
    - Nursing

SCHOOL OF HUMANITIES AND SOCIAL SCIENCES

1. **Department of Criminal Justice**
    - Criminal Justice
2. **Department of English Language and Literature**
    - English Language and Literature
3. **Department of Human Services**
    - Human Services
4. **Department of Humanities and Public History**
    - Public History
5. **Program in Interdisciplinary Studies**
    - Interdisciplinary Studies
6. **Department of Psychology**
    - Psychology
7. **Program in Theatre**
    - Theatre and Media Performance

SCHOOL OF THE SCIENCES

1. **Department of Biological Sciences**
    - Biology
    - Biotechnology
    - Environmental Science
    - Medical Technology
2. **Department of Chemistry**
    - Biochemistry
    - Chemistry
3. **Department of Mathematics and Physics**
    - Applied Mathematics
4. **Department of Nursing**
    - Nursing

4.3 DEFINITION OF FACULTY, FACULTY RANK AND FACULTY TITLES

Definition of Faculty

- The faculty of Stevenson University are employees who hold academic rank and whose primary appointment is to serve students through instruction, guidance of experiential learning activities, academic advisement, and other forms of learning. The faculty includes those members who perform duties in service as department chairs and program coordinators if they otherwise fulfill the definition immediately above. For the definition of faculty who are eligible for voting memberships in the Faculty Council pursuant to the Faculty Council Constitution and Bylaws see Volume I, Section 4 E.

- Administrators may hold faculty status but shall not be considered faculty under the constitution of the Faculty Council. In accordance with the University's standards, the Executive Vice President for Academic Affairs and the President shall award initial ranking at the time of employment. Administrators who return to full-time faculty status may retain their academic rank.

Faculty Rank

The titles Professor, Associate Professor, Assistant Professor, Instructor, and Senior Lecturer/Lecturer indicate full-time appointments to the instructional faculty. The titles Adjunct Professor and Adjunct Instructor indicate part-time appointments to the instructional faculty. In accordance with the University's standards, the Executive Vice President for Academic Affairs and the President award initial ranking at the time of employment. Thereafter, faculty may apply for advancement in rank through the formal application process. Faculty members holding the rank of Senior Lecturer cannot be promoted; however, they may apply for open positions at higher ranks in accordance with the faculty search process.

Special-Appointment Faculty

Artist/Writer/Scholar-in-Residence

The University may appoint artists, writers, scholars and other distinguished individuals to the special-faculty status of Artist/Writer/Scholar-in-Residence. Such appointments are awarded for a specific period of time and may be full time or adjunct depending upon the needs of the University. They are appointed by the Executive Vice President for Academic Affairs after consultation with the applicable School Dean. All such faculty are hired for a limited period of time with no intent of ongoing employment.

Long-Term Contracts for Full-Time Faculty

Stevenson University introduced Long-Term contracts for full-time faculty effective July 1, 2007. Full-time faculty members will receive annual contracts for the first three years of employment based on the outcome of her/his annual performance appraisal. In the third year, the faculty member will be offered either a three-year contract or a one-year interim contract. On completion of the third year of a three-year contract, and following her/his annual performance appraisal, the faculty member will be offered a five-year contract or a one-year interim contract based on performance. Once the five-year contract is completed, and after the fifth year's performance appraisal, the faculty member will receive another five-year contract or a one-year interim contract. The contract renewal process will repeat itself indefinitely. After a maximum of two consecutive one-year interim contracts, the faculty member will receive either a long-term contract or notification of non-reappointment. The contracts define "cause" for non-reappointment as well as dates of notification in cases of non-reappointment.

Contract evaluations will be based on Faculty Evaluation System standards. However, when evaluations for contract renewal and promotion occur at the same time, faculty who receive promotion will automatically be given an appropriate contract renewal.

Sample Long-Term Contract Process

SU faculty will be granted one of five contracts:

- **Year-to-year:** New faculty who are in their first three years of service at the University, or current faculty without sufficient years of service to be granted a long –term contract

- **Three-year:** Faculty whose contract extends for a total of three years after which a five-year contract or a one-year interim contract may be offered

- **Five-year:** Faculty whose contract extends for a total of five years after which either a five-year or a one- year interim contract may be offered
- **Interim year:** Faculty who have more than three years of service but who have not been granted a three-year or five-year contract (A maximum of two interim contracts may be offered to a faculty member before the offer of a long–term contract or non-reappointment notification.)
- **Non-reappointment year:** Faculty who have been notified of non-reappointment.

4.4 CRITERIA FOR FACULTY RANK

Full-Time Faculty

Professor

The Standards that have to be met for the rank of Professor are:

Academic Preparation: Doctorate or terminal degree

Professional Experience: Minimum of nine years successful full-time* university teaching (or equivalent) including at least four years teaching at Stevenson University. Three of those four years at Stevenson University must have been served at the Associate Professor level. **

*Adjunct faculty service at SU may be translated into years of full-time service for the purpose of determining eligibility for promotion according to this formula: 30 credit hours or the equivalent of adjunct faculty service equals one year of full-time service.

1. No more than 60 credit hours or their equivalent may be applied to the service requirements for promotion.

2. No fewer than 30 credit hours or their equivalent may be applied to the service requirements for promotion. Only one year of full-time service may be credited for 30 to 59 credit hours (See also Faculty Promotions in Section 4.6).

** In the case of new hires with substantial teaching experience at another institution, the requirements for years of teaching at SU, at this and other full-time ranks, may be waived at the discretion of the Executive Vice President for Academic Affairs.

Professional Competence and Scholarship: Achievement of superior breadth and depth of knowledge in the field, as evidenced by such things as (but not limited to) continuing study (credit or non-credit) in the discipline, conference presentations, conference attendance, publications, poster sessions, exhibitions, creative performances, editorships or curatorships, academic awards and recognition, software development, course development. Faculty member shows consistent manifestation of professional growth and scholarly activity.

Teaching Effectiveness: Superior level of teaching proficiency, as evidenced by such things as (but not limited to) implementation of innovative teaching methods or course enhancements (including technology enhancements), attendance at faculty workshops,

facilitation of faculty workshops, positive student and peer evaluations, teaching awards and recognition, letters of commendation from Department Chairs, Program Coordinators, or School Deans.

Service to University and Profession: Outstanding leadership and creative contribution to the total objectives of the university, and to the profession as a whole, including such things as outstanding service on committees, high commitment to and superior effectiveness in student advising, mentoring of students or peers beyond routine duties (e.g. PASS program mentor, new faculty mentor), special service that enhances the campus mission or efficiency, service to external agencies related to the University (e.g. Middle States evaluator), active involvement in professional associations (e.g. serving on association Subcommittees or holding office in a professional association), active involvement in the campus culture (e.g. campus life, university events, cultural events, and sporting events).

Associate Professor

The Standards that have to be met for the rank of Associate Professor are:

Academic Preparation: Doctorate or terminal degree (see also Faculty Promotions Section 4.6).

Professional Experience: Minimum of six years successful full-time* (or equivalent) university teaching, including at least four years full time at SU. Two of those years at Stevenson must have been served at the Assistant Professor level. **

* For formula used to count adjunct teaching toward the minimum at SU, see note under Professor rank.

** In the case of new hires with substantial teaching experience at another institution, the requirements for years of teaching at SU, at this and other full-time ranks, may be waived at the discretion of the Executive Vice President for Academic Affairs.

Professional Competence and Scholarship: Sustained high level of breadth and depth of knowledge in the field, as evidenced by such things as (but not limited to) continuing study (credit or non-credit) in the discipline, conference presentations, conference attendance, publications, poster sessions, exhibitions, creative performances, editorships or curatorships, awards and recognition, software development, course development. Faculty member shows consistent manifestation of professional growth and scholarly activity.

Teaching Effectiveness: Sustained effort toward and high level of success in improving teaching proficiency, as evidenced by such things as (but not limited to) implementation of innovative teaching methods or course enhancements (including technology enhancements), attendance at faculty workshops, presentation of faculty workshops, student and peer evaluations, awards and recognition, letters of commendation from Department Chairs, Program Coordinators, or School Deans.

Service to University and Profession: Evidence of leadership and creative contribution to the total objectives of the university, and to the profession as a whole, including such service as significant involvement in committee work, high level of effectiveness in student advising, efforts to mentor students or peers beyond routine duties (e.g. PASS program mentor, new faculty mentor), service to external agencies related to the University (e.g. Middle States evaluator), active involvement in professional associations (e.g. serving on association Subcommittees or holding office in a professional association).

Assistant Professor

The Standards that have to be met for the rank of Assistant Professor are:

Academic Preparation: Doctorate or terminal degree (see Faculty Promotions, Part C); or Master's degree plus 30 additional graduate credits indicating continued study in the field; or equivalent certified specialization with three years successful full-time* university teaching experience at SU.

*For formula used to count adjunct teaching toward the minimum at SU, see note under Professor rank.

Professional Experience: Prior teaching experience at the university level preferred but not required.

Professional Competence and Scholarship: Proven competence in one's area of specialization, as evidenced by such things as (but not limited to), conference presentations, conference attendance, publications, poster sessions, exhibitions, creative performances, editorships or curatorships, awards and recognition, software development, course development. Faculty member shows evidence of professional growth and scholarly activity.

Teaching Effectiveness: Sustained effort toward improving teaching proficiency, as evidenced by such things as (but not limited to) implementation of innovative teaching methods or course enhancements (including technology enhancements), attendance at faculty workshops, presentation of faculty workshops, student and peer evaluations, awards and recognition, letters of commendation from Department Chairs, Program Coordinators, or School Deans.

Service to University and Profession: Evidence of capacity for leadership and creative contribution to the total objectives of the university, and to the profession as a whole, including such service as regular involvement in committee work, commitment to and effectiveness in student advising, efforts to mentor students beyond routine duties (e.g. PASS program mentor), service to external agencies related to the University (e.g. Middle States evaluator), active involvement in professional associations (e.g. serving on association Subcommittees or holding office in a professional association).

Instructor

The Standards that have to be met for the rank of Instructor are:

Academic Preparation: Minimum of a master's degree; or equivalent certified specialization; or equivalent professional expertise.

Professional Experience: Prior teaching experience at the university level preferred but not required.

Professional Competence: Competence in and commitment to professional growth in one's area of specialization; interest in continued professional development, including such things as involvement in professional associations.

Teaching Effectiveness: Evidence of interest in, and the ability to communicate with the student. Faculty member shows the capacity to encourage students and promote effective learning. Commitment to continued improvement of teaching proficiency.

Service to University and Profession: Willingness to contribute to the University community by participating actively in committees and campus activities. Faculty member shows a willingness to collaborate with faculty and staff to promote the goals of the university.

Effective August 2015, the rank of Instructor will be discontinued for all new appointments.

Faculty hired prior to August 2015 who hold the rank of Instructor are exempted from the requirement that it be a visiting, limited term appointment.

Senior Lecturer/Lecturer

The standards that have to be met for the rank of Senior Lecturer/Lecturer are:

Academic Preparation: Minimum of a master's degree; or equivalent certified specialization; or equivalent professional expertise.

Professional Experience: Prior teaching experience at the university level preferred but not required.

Professional Competence: Competence in and commitment to professional growth in an appropriate area of specialization.

Teaching Effectiveness: Since the focus of faculty members holding this rank is teaching, strong evidence of interest in communicating with students and facilitating learning is paramount. A commitment to continued improvement of teaching proficiency should also be demonstrated.

Service to the University and Profession: Service as an academic advisor is required.

Levels: "Senior Lecturer" designates Lecturers holding a terminal degree or those who have served in this rank for six or more years. Lecturers who serve six years in the rank automatically attain the level of Senior Lecturer beginning in the seventh year of service.

Visiting Faculty

Appointment as a full-time visiting faculty member can be made at the rank of Visiting Professor, Visiting Associate Professor, Visiting Assistant Professor, or Visiting Instructor in accordance with the criteria set forth above for these ranks. The visiting faculty appointment is for one year.

Adjunct Faculty

Adjunct Professor

The Standards that have to be met for the rank of Adjunct Professor are:

Academic Preparation: Doctorate or terminal degree OR minimum of Master's degree or equivalent certified specialization AND successful university teaching experience at SU after teaching the following credit hours:

- *54 credit hours at the standard adjunct load, or*

- *66 contact hours for those who teach in Mathematics, or*
- *72 contact hours for those who teach in Laboratory Sciences, Film/Video, Theater, and Visual Communication Design.*

Or minimum of Master's degree or equivalent certified specialization and 5 years successful university teaching experience at SU.

Professional Competence: Shows competence and commitment to professional growth in one's area of specialization; interest in continued professional development, including such things as involvement in professional associations.

Teaching Effectiveness: Shows evidence of interest in, and the ability to communicate with the student. Faculty member shows the capacity to encourage students and promote effective learning. Shows commitment to continued improvement of teaching proficiency.

Service to University and Profession: Shows willingness to contribute to the University community and/or the professional community as demonstrated by participating in university and/or professional activities. Faculty member shows a willingness to collaborate with others to promote the goals of the university.

Adjunct Instructor

The Standards that have to be met for the rank of Adjunct Instructor are:

Academic Preparation: Minimum of master's degree or equivalent certified specialization.

Professional Competence: Competence in one's area of specialization; interest in continued professional development, including such things as involvement in professional associations.

Teaching Effectiveness: Evidence of interest in and the ability to communicate with the undergraduate student. Commitment to continued improvements in teaching proficiency and to promoting student learning.

Service to University and Profession: Shows willingness to contribute to the University community and/or the professional community as demonstrated by participating in university and/or professional activities. Faculty member shows a willingness to collaborate with others to promote the goals of the university.

4.5 EVALUATION CRITERIA

All members of the teaching faculty are subject to annual evaluation. A multifaceted system of evaluation has been developed by the Faculty Council and approved by the President. This system bases evaluation on a number of criteria and culminates in annual performance reviews conducted by the first-line supervisor (Program Coordinator, Department Chair, Associate Dean or School Dean).

4.6 FACULTY PROMOTIONS

Faculty members who believe they should be promoted should first consult the eligibility requirements listed as "Criteria for Faculty Rank" listed in this handbook and confirm their eligibility with the Executive Vice President for Academic Affairs' Office.

If eligible, the faculty member should submit a Professional Portfolio to his or her immediate supervisor (Program Coordinator, Department Chair, Associate Dean or School Dean as appropriate) on or before one week prior to the start of classes of the spring semester of the fiscal year prior to the fiscal year in which the promotion would be effective. Two weeks after submission of the Professional Portfolio to the immediate supervisor, the immediate supervisor will forward the Professional Portfolio to the appropriate School Dean. The School Dean will review the Professional Portfolio and any supporting evidence and send the Professional Portfolio and a written evaluation to the Executive Vice President for Academic Affairs' Office for consideration three weeks after the School Dean receives the Professional Portfolio from the immediate supervisor. (The applicant may view this evaluation letter.) The Executive Vice President for Academic Affairs will make the Professional Portfolio, any supporting evidence and the School Dean's recommendation available to the Promotions Review Board.
The Professional Portfolio is the formal application and is comprised of a:

1. Letter of Application
2. Cumulative Faculty Record
3. Copies of each of the following items from the previous three years:
    a. Student Evaluation Results with comments
    b. Response to Student Evaluation forms – every semester*
    c. Syllabi – Representative sample of each course taught
    d. Classroom Observation forms –*
    e. Performance Appraisals – annual*
    f. Professional Development Plans – annual*

*These required items are more fully described in the Faculty Evaluation System documents. Supplemental documentation may include:

Teaching philosophy statement, sample assignments, samples of student work, evidence of special service to professional associations, and other documentation that highlights one's teaching approach, creativity, and professional growth. The applicant may also request a letter of recommendation from their immediate supervisor or any other relevant person.

An earned doctorate constitutes a terminal degree. In the case of academic fields in which the Executive Vice President for Academic Affairs determines that doctorates are not widely offered by universities in the United States, an appropriate master's degree satisfies the requirement for a terminal degree. The Promotions Review Board will make a recommendation to the Executive Vice President for Academic Affairs.

The Executive Vice President for Academic Affairs will review the recommendations and then submit the final recommendations for promotion to the President.

The Executive Vice President for Academic Affairs will notify each candidate of the promotion determinations on request, any candidate who has not been recommended will be provided with an opportunity for a conference with the Executive Vice President for Academic Affairs for the purpose of discussing the reasons for denial, areas of weakness, and improvements necessary.

Full-time faculty members holding the rank of Assistant Professor or higher will become Adjunct Professors if they change their status from full-time to adjunct.

Implementation

Eligible faculty members are not obligated to apply for promotion. There will be no limit on how many times faculty members may apply for a desired promotion.

4.7 NEW FACULTY ORIENTATION

Faculty Orientation Guidelines for Full-Time Faculty

New Faculty Orientation (NFO) is an orientation program for new fulltime faculty and academic administrators. These new employees meet weekly with a member of the administration in the fall semester of their first year to learn about the policies and procedures at Stevenson and the functions and responsibilities of various campus offices. In addition to familiarizing the new employees with important information about the university, the program allows them to form a network of colleagues and to have their questions and concerns addressed.

Additional training is required for those who teach online courses. This training is provided by the Distance Learning office in the School of Graduate and Professional Studies.

4.8 FACULTY RIGHTS AND RESPONSIBILITIES

Responsibilities of All Full-Time and Adjunct Faculty

1. Adherence to the ethical standards of the teaching profession as defined in this Policy Manual.

2. Teaching assigned classes in accordance with the Stevenson University Catalog descriptions and the stipulations of the department

3. Employing methods designed to maximize student learning.

4. Notifying the Office of Academic Support whenever it appears that a student's repeated absence or performance is endangering the student's success.

5. Holding classes for the full scheduled number of minutes and in the room assigned by the Registrar.

6. Informing students of the time(s) and location of scheduled office hours and holding at least three scheduled office hours per week.

7. When the absence is known in advance, arranging for a substitute instructor or rescheduling the class, with the approval of the Department Chair, Program Coordinator, Associate Dean, or School Dean.

8. Submitting to the office of the School Dean by the requested dates the:
   a. syllabus for each course
   b. textbook selection for each course

9. Gaining familiarity with the information in the University Catalog and the Stevenson Policy Manual.

Additional Responsibilities of Full-Time Faculty

In addition to the responsibilities noted in Subsection 4.7 above, full-time faculty are responsible for:

1. Maintaining standards of teaching worthy of accreditation; seeking to improve instruction through the best current practices as demonstrated by professional

development activities, departmental recommendations, and advice of the Faculty Mentoring Evaluation Committee.

2. Participating in departmental, School or University-wide faculty meetings; assuming responsibility for attendance and for an equitable share of the work, including the taking and proper disposal of minutes.

3. Attending in academic garb the annual Convocation, the Winter Commencement, and at least one of the three May Commencement ceremonies.

4. Adhering to the Outside Employment Policy.

5. Participating in the orientation activities of the University.

6. Participating in the academic advising of students.

7. Continuing to participate in professional development activities.

Academic Freedom

Stevenson University subscribes to the following definition of academic freedom contained in the American Association of University Professors' 1940 Statement of Principles on Academic Freedom and Tenure:

Institutions of higher education are conducted for the common good and not to further the interest of either the individual teacher1 or the institution as a whole. The common good depends upon the free search for truth and its free exposition.

Teachers are entitled to full freedom in research and in the publication of the results, subject to the adequate performance of their other academic duties; but research for pecuniary return should be based upon an understanding with the authorities of the institution.

Teachers are entitled to freedom in the classroom in discussing their subject, but they should be careful not to introduce into their teaching controversial matter that has no relation to their subject.[1]

Limitations of academic freedom because of religious or other aims of the institution should be clearly stated in writing at the time of the appointment.[2]

The University and university teachers are citizens, members of a learned profession, and officers of an educational institution. When teachers speak or write as citizens, they should be free from institutional censorship or discipline, but their special position in the community imposes special obligations. As scholars and educational officers, they should remember that the public may judge their profession and their institution by their utterances. Hence, they should at all times be accurate, should exercise appropriate restraint, should show respect for the opinions of others, and should make a demonstrable effort to indicate that they are not speaking for the institution.

Statement of Professional Ethics

[The statement that follows is a revision of a statement originally adopted in 1966 that was approved by the American Association of University Professors, Committee on Professional Ethics. It was adopted by the Association's Council in June 1987 and endorsed by the Seventy-third Annual Meeting.]

1. 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 subject is to seek and to state the truth as they see it. To this end professors 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 professors may follow subsidiary interests, these interests must never seriously hamper or compromise their freedom of inquiry.

2. As teachers, professors encourage the free pursuit of learning in their students. They hold before them the best scholarly and ethical standards of their discipline. Professors demonstrate respect for students as individuals and adhere to their proper roles as intellectual guides and counselors. Professors make every reasonable effort to foster honest academic conduct and to ensure that their evaluations of students reflect each student's true merit. They respect the confidential nature of the relationship between professor and student. They avoid any exploitation, harassment or discriminatory treatment of students. They acknowledge significant academic or scholarly assistance from them. They protect their academic freedom.

3. As colleagues, professors have obligations that derive from common membership in the community of scholars. Professors do not discriminate against or harass colleagues. They respect and defend the free inquiry of associates. In the exchange

of criticism and ideas, professors show due respect for the opinions of others. Professors acknowledge academic debt and strive to be objective in their professional judgment of colleagues. Professors accept their share of faculty responsibilities for the governance of their institution.

4. As members of an academic institution, professors seek above all to be effective teachers and scholars. Although professors observe the stated regulations of the institution, provided the regulations do not contravene academic freedom, they maintain their right to criticize and seek revision. Professors give due regard to their paramount responsibilities within their institution in determining the amount and character of work done outside it. When considering the interruption or termination of their service, professors recognize the effect of their decision upon the program of the institution and give due notice of their intentions.

5. As members of their community, professors have the rights and obligations of other citizens. Professors measure the urgency of these obligations in the light of their responsibilities to their subject, to their students, to their profession and to their institution. When they speak or act as private persons, they avoid creating the impression of speaking or acting for their university. As citizens engaged in a profession that depends upon freedom for its health and integrity, professors have a particular obligation to promote conditions of free inquiry and to further public understanding of academic freedom.[3]

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[1] The intent of this statement is not to discourage what is "controversial." Controversy is at the heart of the free academic inquiry that the entire statement is designed to foster. The passage serves to underscore the need for teachers to avoid persistently intruding material that has no relation to their subject.

[2] There are no limitations of academic freedom at Stevenson University other than such teaching as would deny the principle of human dignity (and consequently, of human freedom itself). Stevenson University respects and guards every serious search for truth. Moreover, because Stevenson University is committed to the furtherance of human dignity and freedom, it indoctrinates nothing; rather, it has confidence in the power of the human intellect and spirit increasingly to apprehend truth, which is best sought after honestly, without pressure and in the atmosphere of rational freedom.

[3] Faculty Handbook of Stevenson University, revised August 2002, pages 10-11.

Faculty Appeals Policy

(updated with editorial changes approved by the Faculty Welfare Committee, February 20, 2015)

Faculty have the right to seek a fair hearing regarding their performance and conduct as reflected in the Faculty Performance Appraisal. The Faculty Appeals procedure provides a method for voicing concerns when discussions between faculty and their supervisor have not been successful

in resolving differences. Every attempt should be made to reconcile differences of perception at the faculty-supervisor level before proceeding to the appeals level.

Procedure

1. When a Faculty Performance Appraisal has been completed and faculty have submitted comments reflecting a difference of opinion with the supervisor, a meeting should be held between both parties to discuss a possible reconciliation. Efforts to reconcile differences between the supervisor and faculty will occur at the School level, when applicable, prior to advancing to the appeals process.

2. In the event that reconciliation has not occurred, the faculty member has one month to submit a written request for an appeal hearing to the Executive Vice President for Academic Affairs.

3. The request will be forwarded to the Appeals Subcommittee of the Faculty Welfare Committee for scheduling of a hearing which should be held within one week if possible. The Faculty Welfare Committee will establish the Appeals Subcommittee on an as needed basis. A written notice of the appeals hearing will be sent to the faculty member and the designated contact person on the Appeals Subcommittee.

4. The chair of the Appeals Subcommittee will schedule an appeals hearing. The faculty member and supervisor will be notified of this date.

5. Two weeks prior to the hearing, the faculty member will submit documentation to support his/her appeal to the designated contact person on the Appeals Subcommittee. These materials will be kept confidential through the office of the Executive Vice President for Academic Affairs and will be on reserve checkout.

6. Prior to the appeals hearing, members of the Appeals Subcommittee will review the documents submitted to support the appeal.

7. The appeals hearing will be closed to the public with only committee members, the appealing faculty member, and the supervisor present. Additional testimony may be offered by faculty members invited by the appealing faculty member.

8. During the appeals hearing, the appealing faculty member will testify and include other testimonies as appropriate.

9. After the discussion with the faculty member and supervisor has been completed, the committee will hold a closed session to review the documents/testimony. The committee will offer a recommendation to the Executive Vice President of Academic Affairs.

10. The Executive Vice President of Academic Affairs will review the recommendation from the committee and the appeals documentation submitted by the faculty member. Further conversations with the faculty member and supervisor may be requested.

11. Within two weeks, the Executive Vice President of Academic Affairs will provide a written decision to the faculty member and supervisor.

Faculty Attendance at Commencements and Convocations

Full-time faculty are required to attend the fall convocation ceremony, the Winter Commencement, and at least one of the three May Commencement ceremonies. Adjunct faculty are invited to attend convocation and commencement ceremonies.

Support for Faculty Attendance/Participation at Professional Conferences

Stevenson University faculty are strongly encouraged to attend and actively participate in professional conferences. To that end, the University provides financial support according to guidelines and funding levels established by the Faculty Council and approved by the President. Full-time faculty may receive funding for both conference attendance and for active participation in conferences (e.g., presenting papers, poster sessions). Part-time faculty may receive funding only for active participation in professional conferences. For more information, see guidelines and funding limits provided in this volume under "Funding for Conferences."

4.9 FACULTY DEVELOPMENT

Sabbatical Leave General Guidelines

Purpose

The purpose of granting sabbatical leave is to enhance the faculty member's effectiveness to the University community. The purpose of sabbatical leave shall be the pursuit of study, research, professional writing, curriculum development, approved travel or other activity approved by the Executive Vice President for Academic Affairs. Paid sabbaticals cannot be granted for work toward a terminal degree, such as dissertation writing.

Eligibility for Sabbatical Leave

A faculty member who has served seven consecutive years of full-time service at the University may be considered for sabbatical leave. Approved university leaves-of-absence do not constitute a break in service nor are they credited towards the seven full consecutive years. The term of sabbatical leave will not be credited towards the seven full consecutive years required for a subsequent sabbatical. The academic year immediately following the sabbatical leave will count as the first year to be credited towards subsequent sabbatical leave. Sabbatical and Educational Leave time may not be credited for time served to determine eligibility toward promotion. No candidate may apply for promotion and sabbatical/educational leave in the same year, nor may a faculty member apply for promotion while on sabbatical/educational leave.

Sabbatical leave shall not be regarded as a right to which the employee is entitled. The number of sabbatical leaves granted in a given year is subject to the availability of sufficient funds.

Criteria for Granting Sabbatical Leave

The criteria to be taken into account for granting sabbatical leave include:

1. *The nature of the leave project and its significance to the*
   a. *developmental and instructional programs of the University and/or*
   b. *continued professional development of the candidate*

2. *The employee's years in service and/or prior sabbatical leave, the project's effectiveness and benefit to the University and employee, personal circumstances and commitment to the university; the practical needs of the applicant's department and of the university.*

Faculty and professional members who have not received sabbatical leave do not have automatic priority over those who already have taken one. In instances where two or more candidates meet

all criteria equally and at least one request must be denied because of insufficient funds, the decision will be left to the discretion of the Executive Vice President for Academic Affairs.

Procedure for Requesting Sabbatical Leave

Faculty members applying for sabbatical leave should submit a letter of application to their immediate supervisor one week prior to the start of classes of the spring semester of the fiscal year prior to the fiscal year the sabbatical would be effective. Two weeks after submission of the application to the immediate supervisor, the immediate supervisor will forward the application to the appropriate School Dean with a written recommendation. The School Dean will review the application, the immediate supervisor's recommendation and add a recommendation from the dean. The School Dean will forward the application and the recommendations to the Executive Vice President for Academic Affairs' office three weeks after the School Dean has received the application from the immediate supervisor. The Executive Vice President for Academic Affairs will make the application and the recommendations available to the Promotions Review Board. This written application must clearly and fully explain the specific objective of the leave and request an appropriate level of institutional support (see below). The recommendation of the immediate supervisor should address both the feasibility of the proposal and the benefits that will ultimately accrue to the department.

The recommendation of the School Dean must explain the departmental impact of the leave and the manner and cost of covering for the classes that will be left vacant if the leave is approved.

The application must include the following:

1. State the specific dates for the period of leave.

2. State the specific major objectives to be accomplished during the leave period.

3. Outline the project steps or program of study for each semester on leave.

4. State the anticipated result of the project or study.

5. Add other information, which may be helpful in assessing the value of the leave.

Financial Arrangements for Sabbatical Leave

Salary payments to employees on sabbatical leave will be made on the following basis: full salary for one semester's leave or 5/9 for a one-year leave.

The University continues to pay for all benefits to which the employee is eligible.

Any employment undertaken by the employee on sabbatical leave must be central to the leave project.

Employee Commitment and Expectations for Those Taking Sabbaticals
A faculty member may receive no outside remuneration during the period of sabbatical leave unless such remuneration is a central part of the project or with special permission from the Dean.

For the duration of the sabbatical, faculty will not be expected to perform any administrative duties that are normally part of their jobs. Arrangements should be made prior to the sabbatical to assign these duties to others during the time of the sabbatical.

Faculty members who accept paid sabbatical leave agree to return to full-time employment at SU for the year that follows the leave. Violation of this agreement for a minimum of one year of service makes the recipient of the leave responsible for all salary and financial benefits provided by SU during the period of the sabbatical leave. The Executive Vice President for Academic Affairs may grant exceptions.

NOTE: *Faculty granted sabbaticals are expected to give a presentation to the campus community during the year following the sabbatical leave. This presentation should describe the project conducted during the sabbatical and methodology and/or results and also discuss how the sabbatical experience contributed to the faculty member's intellectual or professional growth. If desired, the faculty member, as part of this presentation, may also address how the work conducted has informed/enhanced his/her approach(es) to teaching.*

Educational Leave General Guidelines

Purpose
SU is committed to retaining and building an excellent faculty. One measurement of excellence is to have a very high percentage of faculty that hold the highest degree in their respective disciplines. A way of achieving this goal is to recruit faculty who hold "terminal" degrees. Another equally important procedure is to support current faculty members in their efforts to complete the degrees they are seeking. For this reason, SU offers a program of educational leave. Occasionally, a faculty member may also use educational leave to prepare for new teaching assignments.

Eligibility
To be eligible for an educational leave, a faculty member must complete a minimum of two years full-time teaching at SU. A faculty member may be granted more than one educational

leave; however, only one leave can be accompanied by salary benefits. Approved university leaves-of- absence do not constitute a break in service nor are they credited towards the seven full consecutive years required for granting sabbaticals. Sabbatical and Educational Leave time may not be credited for time served to determine eligibility toward promotion. No candidate may apply for promotion and sabbatical/educational leave in the same year, nor may a faculty member apply for promotion while on sabbatical/educational leave.

Criteria for Granting Educational Leave

Priority for educational leave will be given to applicants who seek support to complete a thesis or dissertation, fulfill a clinical experience, fulfill a residency requirement, or accomplish another objective to which full-time teaching is an obstacle. The number of educational leaves granted is subject to the availability of sufficient funds.

Procedure for Requesting Educational Leave

Faculty members applying for educational leave should submit a letter of application to their immediate supervisor one week prior to the start of classes of the spring semester of the fiscal year prior to the fiscal year the sabbatical would be effective. Two weeks after submission of the application to the immediate supervisor, the immediate supervisor will forward the application to the appropriate School Dean with a written recommendation. The School Dean will review the application and the immediate supervisor's recommendation and add the dean's recommendation. The School Dean will forward the application and the recommendations to the Executive Vice President for Academic Affair's office three weeks after the School Dean has received the application from the immediate supervisor. The Executive Vice President for Academic Affairs will make the application and the recommendations available to the Promotions Review Board. This written application must clearly and fully explain the specific objective of the leave and request an appropriate level of institutional support (see below). The recommendation of the immediate supervisor should address both the feasibility of the proposal and the benefits that will ultimately accrue to the department. The recommendation of the School Dean must explain the departmental impact of the leave and the manner and cost of covering for the classes that will be left vacant if the leave is approved.

Institutional Support for Educational Leave

An eligible faculty member may apply for an educational leave of one semester with full compensation or one full year with 5/9 salary and full benefits. Alternative forms of support (e.g., reductions in teaching loads or other responsibilities) to assist in the completion of degrees may be arranged without the above procedures; however, these options are never automatic and must receive support from the immediate supervisor, School Deans, Executive Vice President for Academic Affairs, and the President. Faculty members must not have other employment while on educational leave without the written authorization of the Executive Vice President for

Academic Affairs. Faculty members may not be promoted while on educational leave, and the leave period does not count toward the professional experience minimums required for promotion.

Faculty Obligation

For the duration of the educational leave, faculty will not be expected to perform any administrative duties that are normally part of their jobs. Arrangements should be made prior to the sabbatical to assign these duties to others during the time of the sabbatical.

Faculty members who accept paid educational leave agree to return to full-time employment at SU for two years following the leave. This requirement in no way alters any other contractual term such as the length of the contract, although the President of SU does have the discretion to waive or alter the length of service required of a faculty member following educational leave. The recipient's violation of this agreement for a minimum of two years of service makes the recipient of the leave responsible for all salary and financial benefits provided by SU during the period of the educational leave. The recipient is responsible for repayment based on the formula that one-year return service equals one half of the salary and financial benefits provided by the university.

Faculty Conference Funding Guidelines and Application

Guidelines

1. Full-time faculty are eligible to receive funding to either attend or participate in professional conferences. Part-time faculty are eligible to receive funding only if they are participating in a professional conference. Faculty on Sabbatical or Educational Leave are eligible to receive funds while on leave. Funds may be requested for conferences, conventions, or workshops. There is no geographic limit on the requests that may be considered. NOTE: Funding cannot be granted under this program for purely informal travel, graduate work, course tuition for university credit, membership fees, research, or equipment expenses.

2. Faculty who desire funding MUST formally apply prior to the conference by submitting the CONFERENCE FUNDING APPLICATION FORM (FOR FACULTY DEVELOPMENT). No funding will be provided unless this form has been approved.

3. Faculty who wish to receive a paper copy should contact the Associate Vice President for Academic Affairs, or the appropriate SU portal page.

4. Academic administrators (including School Deans, Associate Deans, Department Chairs, and Program Coordinators) do not receive funding through this source. Professional development funds for these academic administrators are allocated in the department and School budgets.

   NOTE: If a faculty member is attending a conference at the request of an academic administrator to further an administrative initiative, funding should come through the department or School budget, not through this source.

5. **Funding:** As of October 2011, the funding limits shown below have been set. Please contact the Associate Vice President for Academic Affairs to confirm that they have not changed.

   Full-time Faculty

   Up to $1000 for attendance at a professional conference/workshop/convention.
   Up to $1500 for participating* in a professional conference.

   Part-time Faculty

   Up to $1250 for participating* in a professional conference.

Participating in a conference means the applicant is presenting a paper, giving a poster presentation, or participating in a panel discussion.

6. There is no limit to the number of events an applicant can attend; however, the total amount that may be allocated to a full-time faculty member cannot exceed the maximum for the year of $1000 (or $1500 for giving a presentation). A part-time faculty member cannot exceed the maximum for the year of $1250 for presenting at a conference or conferences.

7. Expenses that can be reimbursed are: registration fees, travel expenses, hotel accommodations, meals, personal auto, and other specified expenses.

8. For expenses to be reimbursed, the applicant MUST provide ALL receipts. These include sales receipts, checks, and credit card receipts. The Business Office has the final judgment on the acceptability of all receipts. It is the responsibility of the applicant to collect and submit all receipts.

9. If the applicant's personal automobile is used, a record of the mileage must be kept and noted on the reimbursement form. Applicants must able to state their departure

and destination locations. Mileage is distance to place minus normal commuting miles to work. The reimbursement rate is subject to change (check with the Business Office).

10. The fiscal year runs from July 1 to June 30. All reimbursement information (forms and receipts) MUST be received by July 15. No reimbursement can be made if forms and receipts are received after the budget is closed out.

11. Applications will be considered on a first-come, first-served basis, but with preference being given to applications from faculty who are presenting at conferences and to faculty who have not yet received conference funding for the year.

12. To receive the funds awarded, the completed "Request for Reimbursement Form" (with all receipts attached) should be submitted to the Associate Vice President for Academic Affairs, no later than three weeks after the end date of the conference attended.

13. A faculty member who has been awarded funding and is unable to use the approved funds, should immediately notify the Associate Vice President for Academic Affairs.

Instructions for Applicants

1. Complete the Conference Funding Application Form (for Faculty Development) and sign and date it where indicated in Section E. If a copy of the conference program is available, please attach it to your application.

2. Take the completed form to the immediate supervisor (department chair or program coordinator). Discuss the request and, if the supervisor approves the activity, have him/her sign the form in the space provided in Section F.

3. Submit the completed application form to the School Dean, who will evaluate the application according to the following criteria:
    - Does the requested conference/workshop (or related formal activity) contribute to the School or University as a whole?
    - Will it enhance the faculty member's professional ability?
    - Will it be useful in curriculum development?
    - Will the request help the applicant improve teaching-related skills?

4. If the School Dean approves the activity, have him/her sign the application in Section G.

5. Send the signed, approved form to the Associate Vice President for Academic Affairs and retain a duplicate copy of the form. Applicants will be notified in writing of the amount of funding approved and will be sent a "Request for Reimbursement" form to submit along with receipts (and, for those who are presenting, a copy of the program listing the presentation) after the conference.

6. Within three weeks after the conclusion of the conference, submit the Request for Reimbursement form with receipts to the Associate Vice President for Academic Affairs, who will then send it to the Business Office for processing.

Reimbursement covers only amounts for which there are receipts (up to the maximum funding awarded).

Outside Professional and Employment Activities for Full-Time Faculty

Outside professional activities are activities related to the faculty member's academic discipline, and which are administered or sponsored by persons, entities, or governmental agencies other than the University. Outside activities are encouraged by the University where such activities give the faculty member experience and knowledge valuable to professional growth and development and do not conflict with the faculty member's obligations to the University. These activities may help the faculty member to make worthy contributions to instructional programs or to make a positive contribution to the University or the community. Examples of acceptable "outside professional activities" include:

1. Practicing a profession on a part-time basis;

2. Providing professional, managerial, or technical consulting services to an outside entity;

3. Serving on a committee, panel or commission established by an outside entity;

4. Testifying as an expert in administrative, legislative or judicial hearings;

5. Participating in or accepting a commission for a musical, dramatic, dance or other artistic performance or event sponsored by an outside entity;

6. Acting as a reviewer or editor for professional journals or book manuscripts;

7. Presenting occasional lectures or papers at meetings of an outside entity; and,

8. Serving on a corporate or non-profit board.

Before engaging in outside professional activities, the Executive Vice President for Academic Affairs must be apprised of such activities in writing so that they may be duly recognized and documented by the University.

The following University facilities may be used by faculty members in connection with "outside professional activities" without prior approval or reimbursement:

1. Personal office space, excluding personal client interaction;

2. Local telephone calls;

3. E-mail accounts;

4. Personal computers, if available.

No outside professional activity shall be undertaken that might interfere with a faculty member's primary responsibilities to the University. While the faculty member is encouraged to engage in outside professional activities, such activities must be clearly subordinate to his/her teaching, advising, scholarship, and University service responsibilities. Each faculty member is required to receive written permission from the Executive Vice President for Academic Affairs prior to taking on significant other outside activities and/or employment that suggest a conflict regarding the faculty member's obligations to Stevenson University (such as teaching at another institution).

The individual faculty member's contract shall take precedence over anything contained in this policy.

4.10 ACADEMIC LOAD

Full-time Faculty

1. **Purpose:** To direct school deans, associate deans, department chairs, and program coordinators in assigning full-time faculty teaching loads.

2. **Full-time load:** The standard full-time teaching load is defined as follows:
    A. 12 credit/contact hours per semester; 24 credit/contact hours per academic year for Professors, Associate Professors, Assistant Professors, and Instructors.
    B. 15 credit/contact hours per semester; 30 credit/contact hours per academic year for Senior Lecturers /Lecturers and all "Visiting" appointments.
    C. Teaching loads are defined by contact hours rather than credit hours in laboratory science and studio-based programs.

3. **Committee assignments:** All full-time faculty members are expected to participate in faculty governance, serve on departmental committee, and advise students.

4. **Course preparations and new courses:** Course preparations should not exceed more than three per semester.

All faculty members are expected to evaluate and update their courses regularly. Faculty members are encouraged to conceive and develop new courses to expand academic offerings within their respective disciplines.

A. **Course writing or revision:** When course writing or revision is essential for the continued delivery of an academic program and faculty members are asked to develop or revise a course, the School Dean may request that the faculty members be given compensation for their work in the amount of up to $1000 per course. Requests must be approved by the Executive Vice President for Academic Affairs.

B. **Accelerated or online courses**: Compensation for developing an accelerated hybrid course or for redeveloping an online course is $1000. Compensation for developing an online course is as follows:
    - 1 credit (or hour/week) $ 834
    - 2 credits (or hours/week) $1,667
    - 3 credits (or hours/week) $2,500
    - 4 credits (or hours/week) $3,333

- 5 credits (or hours/week) $4,167
- 6 credits (or hours/week) $5,000

5. **Overloads: Faculty may not teach regularly on an overload basis.** Overloads are discouraged as they impede a faculty member's ability to fulfill service, research and professional development obligations.

6. Overloads are allowable only when an overload assignment is absolutely necessary to ensure the quality of the academic program but are never to exceed more than three credit hours or contact hours per semester. **All overload assignments must be approved by the Executive Vice President for Academic Affairs.**

7. Compensation:
   A. Overload Courses: Credit hour overloads will be paid at the adjunct instructor rate for full-time instructors and at the adjunct professor rate for full- time assistant professors, associate professors, and professors.

   Contact hour overloads will be paid at the contact rate. The contact rate is calculated as 75 percent of the adjunct instructor credit hour rate for full-time instructors and 75 percent of the adjunct professor credit hour rate for full-time assistant professors, associate professors and professors.

   B. **Research and Honors Projects:** Whenever possible, teaching of research and honors projects will be organized as courses. Whenever smaller numbers of students enroll for research or honors projects in the sciences in a given semester, compensation is provided on a per student basis ($1500 per student). An alternative recognition of faculty supervision of student projects is a load reduction, but the School of the Sciences Dean must demonstrate the feasibility of such an arrangement prior to the beginning of the semester.

   C. **Directed Studies and Conference Courses:** Directed Studies are individualized courses covering special topics and Conference Courses are courses that are listed in the catalog, that are being taught on an individual basis. These courses will be taught **when necessary** for a student to complete an academic program. These courses require the approval of the appropriate School Dean. Compensation for teaching these courses is $200 per credit hour per student. This procedure does not apply to directing internships, which is covered by a separate policy. (See 5D.)

D. **Directing Internships:** Whenever possible, internships will be organized as courses. Whenever smaller numbers of students enroll in a directed internship, the faculty advisor for that internship will be compensated at the rate of $100 per student.

E. **Credit for Prior Learning Assessment:** The Credit for Prior Learning program offers students a vehicle for converting university-level learning achieved through verifiable professional work experiences and community activities into Stevenson University credit. Students are guided through the process by an academic advisor in The School of Graduate and Professional Studies. Faculty who review a portfolio prepared by the student after completing the PLA 101 course (Portfolio Learning Assessment) will be compensated at the rate of $150 per course per student.

   Whenever a student requests to take a Challenge Examination, faculty will be compensated $150.00 to construct (or revise) and grade the exam.

8. **Reassigned Time:** Faculty members are expected to teach the number of credit and/or contact hours required by the standards established for their department or program. The burden of administrative duties should be carried by the School Deans, department chairpersons, and program coordinators. Faculty members are expected to function as professionals in accordance with the standards established for annual evaluations and promotions; some of these functions fall under categories of service to students, the University, the profession and the community. These regular professional responsibilities are described in contracts and/or policy manuals. Occasionally an extraordinary circumstance may arise (e.g., directing the Middle States accreditation self-study) requiring a temporary load reduction or reassigned time. Such an arrangement must be recommended by the appropriate coordinator, chairperson or director and must be approved by the Executive Vice President for Academic Affairs. Reductions and reassigned time will be kept to a minimum and are awarded only on a semester basis; the Office of the Executive Vice President for Academic Affairs will keep a record of all such arrangements.

Adjunct Faculty

1. **Adjunct Load:** The maximum adjunct teaching load is 9 credit/contact hours per semester; 18 credit/contact hours per academic year.

2. **Committee assignments:** All part-time faculty members are encouraged to participate in faculty governance and serve on departmental committees.

3. **Course preparations and new courses:** All part-time faculty members are expected to evaluate and update their courses regularly. Part-time faculty members are encouraged to conceive and develop new courses to expand academic offerings within their respective disciplines.
    A. **Course writing or revision:** When course writing or revision is essential for the continued delivery of an academic program and part-time faculty members are asked to develop or revise a course, the School Dean may request that the faculty members be given compensation for their work in the amount of up to $1000 per course. Requests must be approved by the Executive Vice President for Academic Affairs.

    B. **Accelerated or online courses:** Compensation for developing an accelerated hybrid course or for redeveloping an online course is $1000. Compensation for developing an online course is the same as for full-time faculty (see above).

4. **Overloads:** Adjunct faculty cannot be assigned course overloads or any employment activities that, when combined with other teaching activities, would meet or exceed the standard full-time load. No adjunct faculty member can teach a full-time load in any given fall or spring semester.

    Adjunct faculty can be assigned Directed Studies, Conference Courses, Senior Research, Honors Projects, Internships, or Credit for Prior Learning Portfolio Assessment provided they do not meet or exceed the standard full-time teaching load. Compensation for these responsibilities will be at the same rate(s) described for full-time faculty.

Special Appointment Faculty

The University may make other special appointments to fulfill needs that cannot be met through regular faculty appointments or to take advantage of significant opportunities to enhance the academic program. Examples of such appointments include visiting faculty positions, faculty exchanges, and special arrangements to meet shortages in the pool of traditional applicants. The Executive Vice President for Academic Affairs makes these appointments after consultation with the applicable School Dean. They are for a limited period of time until the needs can be met through regular faculty appointments or until the special circumstances are no longer present. Special appointment faculty do not have Voting Faculty status, do not serve on faculty

committees, and are exempt from academic advisement duties. The Faculty Welfare Committee of the Faculty Council shall be informed of all special appointments.
Workload for special appointment faculty is specified in individual contracts that are approved by the Executive Vice President for Academic Affairs.

Questions or concerns about the guidelines should be brought to the attention of the Faculty Welfare Committee.

4.11 ADDITIONAL ACADEMIC POLICIES

Additional Policies are provided in Volume V - Student Policy Manual.

4.12 FACULTY MENTORING EVALUATION COMMITTEE (FMEC)

The Faculty Council adopted Faculty Mentoring Evaluation Committee guidelines in the spring of 2014. In the wake of that addition, the Faculty Welfare Committee will undertake further revisions in the description and procedures of the Faculty Evaluation System during the 2014-2015 academic year. Additionally, the faculty of each school will develop a Faculty Job Description document appropriate to that school – the School of the Sciences has such a document that will serve as our model for these conversations. There is an expectation that these Faculty Job Descriptions will be completed in the 2014-2015 academic year.

The following forms are located on the Academic Affairs portal site:

- *Cumulative Faculty Record*
- *Syllabus Checklist*
- *Student Course Evaluation Form*
- *Faculty Performance Appraisal Form*

FMEC: Faculty Mentoring and Evaluation Committee Guidelines

Purpose

The purpose of the Faculty Mentoring and Evaluation Committee (FMEC) is to provide each full-time faculty member at Stevenson University with a small group of colleagues who are invested in supporting, guiding, and mentoring the faculty member through his or her process of academic growth and professional development.

It is important to ensure the integrity of this process; therefore, honest, open, and forthright communication is imperative. It is also necessary and important to keep the materials reviewed within the confines of the committee strictly confidential. As such, all committee members will sign a confidentiality agreement.

These FMEC guidelines explicitly acknowledge the responsibility of the Schools of Stevenson University in the faculty promotion process.

Eligibility

A Faculty Mentoring and Evaluation Committee (FMEC) will be established for each full-time faculty member in the University (hereby referred to as "candidate") who is promotable in terms

of faculty rank. (Promotion eligibility is defined in the University's policy manual, and evaluative criteria for promotion are defined by the candidate's school.)
A Faculty Mentoring and Evaluation Committee (FMEC) may be established for each full-time faculty member who is not promotable in terms of faculty rank upon his/her request. (Promotion eligibility is defined in the University's policy manual, and evaluative criteria for promotion are defined by the candidate's school.)

Composition and Appointment of the FMEC
The FMEC will consist of one faculty member from any department within the candidate's own school and the appropriate department chair, program coordinator, or immediate supervisor. A third member of the committee may be from outside the individual's own department and may be outside the candidate's school if needed to meet committee requirements, or if requested by the candidate.

Additionally, at the discretion of the candidate and committee, a fourth member may be sought from outside the University if that member is beneficial to the candidate's professional development. This member is considered to be 'ex officio' and non-voting. This member is neither held to the same responsibilities as the core three members.

At least one of the faculty members serving on the FMEC must be at or above the rank being sought by the candidate. This requirement cannot be satisfied by a non-voting member.

The Faculty Mentoring and Evaluation Committee (FMEC) will be selected by the following process:

- *The candidate and his/her department chair, program coordinator, or immediate supervisor will meet together to generate a list of faculty members best suited to serve on the committee.*

- *The dean will coordinate the final selection process in order to balance requests made of senior faculty members. The dean will contact faculty members, in writing, with the request to serve. The faculty member may accept or decline this request.*

- *Once the FMEC is established, the candidate will be notified by the dean. Scheduling FMEC meetings will be the responsibility of the candidate.*

At the first meeting of an FMEC, the chair of the committee will be selected. (Note: the department chair, program coordinator, or immediate supervisor may not serve as the FMEC chair.)

The candidate reserves the right to meet with his/her department chair, program coordinator, or immediate supervisor to discuss changes to the composition of the FMEC at any time. In the event an FMEC member leaves SU, the committee member must be replaced, following the previously described guidelines for membership composition. Any changes for any reason to the membership of the committee must be approved by the dean.

Role and Duties of the FMEC

The FMEC will meet with the faculty member at least once annually. The faculty member must permit his/her FMEC to review assessment results, including, but not limited to, student evaluations, the annual performance appraisal, and the annual professional development plan. At the discretion of the candidate, the FMEC chair may be requested to provide a written summary of (or minutes from) each meeting to the faculty candidate and/or committee members. These minutes will remain confidential and become part of the committee record.

If the faculty member is applying for promotion, then the FMEC will meet with him/her more frequently, according to the needs of the candidate. It is expected that the FMEC will hold a lengthy meeting with the faculty member early in the fall semester prior to promotion, followed by at least one additional meeting prior to the date that the promotion application and portfolio are due to the department chair, program coordinator or immediate supervisor. At this time, the FMEC may review the final application portfolio prior to its submission. The FMEC chair will draft a letter on behalf of the committee, regarding the promotion application to the Promotions Review Board, relying on substantive input from all committee members, which will evaluate the faculty member's qualifications for promotion, as described in the University job description and the evaluative criteria set forth by the candidate's school. Final approval of the letter that is to be included in the promotion portfolio will be by majority of all voting committee members. If a committee member is not in agreement with the letter, he/she need not sign off on it. This letter is intended to replace the letter formerly drafted by the candidate's department chair, program coordinator, or immediate supervisor. The candidate reserves the right to inspect the FMEC letter before the portfolio is submitted to his/her department chair, program coordinator, or immediate supervisor.

Those who serve on the Faculty Mentoring and Evaluation Committees will understand their responsibilities. They will be expected to prepare for the meetings and to offer substantive mentoring and evaluative feedback for the candidate's professional development.

The deadline for establishing the Faculty Mentoring and Evaluation Committee (FMEC) for faculty without an FMEC is within the first contract year of attainment of a promotable rank. This deadline applies to newly hired faculty and existing faculty members who are newly eligible

for promotion. It is recommended that faculty members who are not required to, but wish to avail themselves of this opportunity, should follow these guidelines. The first FMEC meeting must also occur within the first year of attainment of a promotable rank.

NOTE: *The FMEC process will be reviewed by the Faculty Welfare Committee of Faculty Council every year, or earlier by request of faculty members. Revisions will be made as warranted.*

4.13 FACULTY EVALUATION SYSTEM

Purpose

To be effective teachers, we strive to do the best for students through our classroom instruction. The following system of faculty evaluation provides a vehicle for the documentation of successful teaching and for the citation of areas where instructional improvement is being undertaken. All faculty, full-time or adjunct, are expected to be actively documenting their performance and working to expand their competence as instructors.

Faculty Evaluation Components

As previously established, the criteria for faculty rank establishes faculty categories. The criteria for faculty include academic preparation, professional experience, professional competence and scholarship, teaching effectiveness, and service to the University and the profession. The faculty evaluation system, presented here, incorporates the same criteria.

A. **Academic preparation** – Faculty should possess the academic credentials in their rank as stated in the Guidelines for Promotion, Sabbatical and Educational Leave. This information will be documented in the curriculum vitae/resume of each faculty member and be reflected in the Cumulative Faculty Record.

B. **Professional experience** – This component is based on the number of years of successful teaching at Stevenson University and at other institutions. (Refer to the Guidelines for Promotion, Sabbatical, and Educational Leave.)

C. **Professional Competence and Scholarship** – Faculty are expected to continue their professional growth through a variety of activities at the University or in other professional arenas. This information will be documented in the curriculum vitae/resume of each faculty member and be reflected in the Cumulative Faculty Record. As cited in the Guidelines for Promotion, Sabbatical and Educational Leave, this category is based on breadth and depth of knowledge in the field.

D. **Teaching Effectiveness** – Teaching effectiveness will be determined in three ways: student evaluation, administrative evaluation and faculty self-evaluation. As cited in the Guidelines for Promotion, Sabbatical and Educational Leave, this category is based on teaching proficiency. See chart below for an explanation of this area of evaluation. (Not all areas required for adjunct)

E. **Service to the University and Profession** – This information will be documented in the curriculum vitae/resume of each faculty member and be reflected in the Cumulative Faculty Record.

As cited in the Guidelines for Promotion, Sabbatical and Educational Leave, this category is based on leadership and contribution to the university. (Not required for adjunct)

[Access to all requisite forms and a general overview of the Faculty Evaluation System is provided in the faculty section of the SU portal.]

Activities Related to Professional Competence/Scholarship, Teaching Effectiveness, and Service to the University/Profession

Sources of Evaluation Data	Activities	Use of Data
Student Evaluation of Course and Faculty	Student evaluations	Faculty/Administration
	Faculty response to student evaluations	Faculty/Administration
	Teacher-initiated assessments that provide feedback on classroom activities	Faculty
Administration Evaluation of Course and Faculty	Review of course syllabi and objectives	Faculty/Administration
	Classroom Visits*	Faculty/Administration
	Performance appraisals (with faculty	Faculty/Administration
Faculty Self- Evaluation	Review of course syllabi & objectives	Faculty/Administration
	Self-assessment (optional)	Faculty
	Teaching philosophy/portfolio (only required for promotion)	Faculty/Administration
	Faculty development plans	Faculty/Administration
	Peer mentoring for new faculty	Faculty
	Peer mentoring between colleagues	Faculty

Full professors will be visited at a minimum of every three years. Associate professors will be visited at a minimum of every two years. Assistant professors and instructors will be visited annually. Faculty applying for promotion should be visited in the year prior to their application for promotion. The Executive Vice President for Academic Affairs will provide an annual report of the implementation of this process to Faculty Welfare Committee.

Understanding the Process of Evaluating Teaching Effectiveness

The following describes the conceptual basis for promoting teaching effectiveness and implementing a formal system of faculty evaluation. Elements referred to below will be supported by faculty development. The ideas noted are adapted from *Improving University Teaching: Strategies for Developing Instructional Effectiveness* by Mary Ellen Weimer.

Developing Instructional Awareness

Goal: To enlarge and clarify one's personal understanding of how one teaches activities

- Self-assessment tools may be used to identify preferred teaching styles, learning styles and teaching goals. The insights gained through self-assessment can assist faculty to clarify goals, reflect on the teaching/learning process, and make connections between their teaching philosophy and practice.

- With the benefit of these insights, faculty will be able to develop/refine their teaching philosophy, which is the initial step in developing a teaching portfolio.

- A review of course syllabi and materials provides the opportunity for refinement of teaching/learning strategies and infusion of new initiatives to improve instructional effectiveness.

Gather Information

Goal: To acquire information on the effectiveness of one's own teaching and to use this as a foundation for future developments.

Activities:

- One source of information will come from student course evaluations. As student responses are reviewed, faculty can reflect on the course and the learning experiences of the class. To capture the essence of this reflection, faculty will complete the Faculty Response to Student Evaluations form to identify instruction elements that should be replicated and possible areas for instructional improvement.

- As needed, faculty can solicit current student feedback to assess effectiveness of instruction during the progression of the course. Tools such as "one minute papers" or other classroom assessments may be used.

- Faculty also will collect materials into a teaching portfolio that can be reviewed during performance appraisals and promotion. The teaching portfolio process enables the teacher to gather materials that reflect his or her teaching practice and highlight areas of excellence and areas for future growth.

- All new faculty will be provided a peer mentor in the department or within a related discipline to assist them in their transition. Mentors will familiarize the new faculty member with teaching at Stevenson and assist in answering basic questions on student composition, course preparations, etc. New faculty will have access to materials on effective teaching through print and online faculty development publications and through faculty workshops and teaching circles or peer focus groups.

Identify Areas for Enhancement or Improvement

Goal: To identify and enhance positive teaching activities and/or to determine improvements that need to be made.

Activities:

- Using a Faculty Development Plan, faculty can prioritize their professional development activities for the coming academic year. In the plan, they will select a focused area for development and determine strategies that will assist them in meeting this goal. During meetings with their supervisor, faculty can discuss these goals and the support that will be needed.

- New faculty and their mentors may participate in classroom visits to each other's classrooms for the purpose of sharing teaching techniques and providing formative feedback. The success of these visits will be supported by advance planning with specific goals being established. Discussions after the visit will support the experience and growth of both faculty members.

- Administrators will review course syllabi and suggest any necessary augmentations or faculty development needed.

Implement Alterations

Goal: To incorporate enhancements and changes in teaching.

Activities:

- Using the Faculty Development Plan as a guide, faculty will participate in the planned activities and collect information through personal reflection and student feedback.

- Faculty will collect information and materials to include in a teaching portfolio. The teaching philosophy statement previously written should be reviewed and amended as needed. The portfolio will support the faculty in their discussions with supervisors and meet the requirements for application for promotion.

- Faculty will complete the Annual Faculty Record for the year, outlining accomplishments and noting service to the University and professional development activities. This document will assist in providing a historical account of their activities and accomplishments.

Assess Effectiveness

Goal: To determine the impact of the alterations

Activities:

- To obtain a general assessment of teaching effectiveness, classroom visits by administrators will be conducted with advanced scheduling. These visits will be preceded by a discussion about the context of the class session and the related objectives. The supervisor will use a standardized form for the observation to assure equity among faculty. Discipline-specific criteria can be added if the faculty and supervisor have discussed the basis of the observation.

- Administrators and faculty will meet for formal performance appraisals. To assure uniformity, a Performance Appraisal document will be used. Signatures of the faculty and supervisor will be applied to the document. If, after discussion between the faculty member and the supervisor, there is a discrepancy in the perspective of the two persons, a formal written response can be included and forwarded to the VP for Academic Affairs. To conclude the year School Deans will review and sign appraisals.

- Faculty and the supervisor will collaboratively develop the Faculty Development Plan for the following year. In the case that the enhancements were effective, a new plan will be developed to address other areas that may need to be examined.

- A faculty showcase event will be held to highlight novel teaching strategies or creative assignments or assessment techniques. Nominations will be made by supervisors or by faculty colleagues. These nominations will be forwarded to the VP for Academic Affairs and the faculty development subcommittee for selection.

4.14 INSTITUTIONAL REVIEW BOARD

Policies and Procedures Overview

A. Overview

All research carried out by administration, faculty, staff and students associated with Stevenson University (SU) involving human subjects must be conducted using basic ethical principles. These principles include respect for persons, beneficence, and justice. Applications of the basic principles to the conduct of research using human subjects leads to the consideration of the following requirements: informed consent, risk/benefit assessment, the appropriate selection of subjects for research, and confidentiality.

Any human subjects research must comply with federal regulations: Protection of Human Subjects (45 CFR 46) and the Common Federal Rule (Federal Register, June 18, 1991), as amended periodically.

Human subjects research, regardless of funding source, must be reviewed by the Stevenson University Institutional Review Board (IRB; Board) before initiation of a project. The IRB is responsible for monitoring the ethical nature of human subjects experimentation carried out by students and faculty of SU using 45 CFR 46 and the Common Federal Rule (*Federal Register*, June 18, 1991). Further, this committee has the authority to approve, approve conditionally, require modifications to, or disapprove any human subjects research performed under the auspices of SU. The University will be responsible for maintaining the currency of this document and for providing support to the IRB.

The IRB will strictly follow the definitions for human subjects' protection found in Article 102 of the Common Federal Rule.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalized knowledge.

A human subject is 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.

Most research conducted at the SU may be exempt from Institutional Review Board (IRB) review. However, this status can only be established by the chairperson of the IRB after reviewing the research proposal. It is suggested that researchers read the following

criteria for "exempt" status and, if the research project you propose falls under these criteria, complete and submit your proposal to the committee chairperson. You can expect a response from him or her within one (1) month indicating approval, approval with conditions, or disapproval. (If your project does not fall under the criteria for Exempt status, please see the criteria for Expedited Review or Full Board Review and follow the procedures described).

If you are a faculty member requiring your students to conduct research projects for instructional purposes follow the procedure for "Research for Instructional Purposes" as more fully described in a later section of this document.

Purpose, Composition, and Authority of the IRB

A. Purpose of the IRB

The Institutional Review Board is charged with the responsibility for review and approval of all research involving human subjects conducted by members of the Stevenson University community.

The Board is required to determine that: (a) the rights and welfare of the subjects are adequately protected, (b) the risks to subjects are outweighed by the potential benefits of the research, and (c) appropriate informed consent will be obtained.

The records of the Board, including correspondence and statements of acceptance or rejection, are to be retained for a period of three (3) years after the termination of a project.

B. Composition of the IRB

Five (5) voting IRB members will be required for a Full Board Review. They will be appointed by the Executive Vice President for Academic Affairs and will serve for a period of three (3) years with initial members serving a period of 1, 2, or 3 years. This standing board will meet on an ad hoc basis and will include:

1. One member from Sciences or Social Sciences

2. One member from a non-scientific area

3. One member from outside Stevenson University (no affiliation with the school)

4. Two members from any discipline (preferably with some knowledge of scientific research)

*All members of the IRB must complete training on the protection of human participants through the Collaborative Institutional Training Initiative (CITI) Program.

C. Authority of the IRB

1. After requisite review and within thirty (30) days of its submission, the IRB may approve, approve conditionally, require modification to or disapprove a pending proposal.

2. The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with IRB requirements or that has been associated with unexpected harm to subjects. Any suspension or termination of approval shall include a statement of the reasons and be reported promptly to the investigator, appropriate institutional officials, and the funding agency, if applicable.

3. Should the IRB determine that either unethical behavior or misconduct in research has occurred, the chairperson will initiate action as deemed appropriate by a consensus of the sitting IRB in conjunction with the SU administration.

D. IRB Review of Proposals

1. Types of Review

a. Exempt. Exemption from formal review is granted by the chair. In the case of a possible conflict of interest, the chair will appoint another member of the IRB to review the request for exemption. Before a proposal is determined to be exempt from further IRB review, the chairperson of the IRB may request additional information about the proposal, and/or may require changes in the consent form, subject recruitment methods, or other aspects of the procedure. Research may not proceed until the investigator responds to the IRB requirements and receives approval from the IRB chairperson.

b. Expedited. If a proposal is deemed Expedited, it is reviewed by two (2) members of the IRB. These will be the Chair and one other member appointed by the Chair.

c. Full Board Review. All research projects not meeting the criteria for Exempted or Expedited Review must be reviewed by the full IRB. A majority of the IRB members must be present to vote on a proposal requiring Full Board approval.

2. Right to Appeal

If a project is disapproved, the principal investigator has the right of reconsideration. The researcher shall send a letter to the Executive Vice President for Academic Affairs within ten (10) working days of the receipt of disapproval requesting a meeting of the Full Board. The Executive Vice President for Academic Affairs shall request that the Chairperson convene the Board in a timely fashion to consider any additional information supporting the proposal. The decision of the IRB regarding the appeal is final.

E. Approved Proposals

1. Approval expires in one (1) year.

2. It is the IRB's responsibility to ensure that researchers follow the guidelines established in 45 CFR 46, especially 45 CFR 46.116 general requirements for informed consent and the Common Federal Rule, and general requirements for informed consent This applies to research considered to be Exempt from IRB review, as well as research given Expedited and Full Board Reviews. Researchers will make themselves familiar with and agree to abide by 45 CFR 46.116. For proposals offered by student researchers, faculty sponsors must ensure the student has read and understands the federal regulation.

Exempt Review

Criteria for Exempt Status

Research is exempt from further IRB review if it entails no more than "minimal risk" and falls in one or more of the following categories. "Minimal risk" means the risks of harm anticipated in the proposed research are not greater, considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Exempt research categories:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as:

a. research on regular and special education instructional strategies, or

b. research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
   a. information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

   b. any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
   a. public benefit or service programs;

   b. procedures for obtaining benefits or services under those programs;

   c. possible changes in or alternatives to those programs or procedures; or

   d. possible changes in methods or levels of payment for benefits or services under those programs.

6. Taste and food quality evaluation and consumer acceptance studies,
    a. if wholesome foods without additives are consumed, or
    b. if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Procedures for Obtaining Exempt Status

1. Principal investigators of all research, whether funded or not, that involves human subjects must submit two (2) copies of the completed IRB application. The IRB application form is accessible through the SU website – Office of Research & Development site's "Forms and Policies" section.

2. The Chairperson will review the completed IRB application and establish if the proposal is (1) Exempt from IRB review, (2) subject to an Expedited review, or (3) subject to a Full Board review. If exempt, the Chairperson shall so designate, record, and give notice to the principal investigator who can then begin the project.

3. If the investigator needs to make any change in an approved protocol (e.g., change procedures), a new IRB application must be submitted to the IRB for review.

4. Prior to implementing any changes, a new application must be approved by the IRB.

Expedited Review

Criteria for Expedited Review Status

Research activities that (1) present no more than minimal risk to human subjects, and 2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects. The categories in this list apply regardless of the age of subjects, except as noted.

The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

The expedited review procedure may not be used for classified research involving human subjects.

Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Expedited Research Categories

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
    a. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
    b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
    a. (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

    b. from other adults and children2, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means.

    Examples: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing

gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

   Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research

employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

8. Continuing review of research previously approved by the convened IRB as follows:
    a. where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects; or

    b. where no subjects have been enrolled and no additional risks have been identified; or

    c. where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

Procedures for Obtaining Expedited Review Status

1. Principal investigators who believe their projects qualify for an Expedited Review should complete two (2) copies of the IRB application and submit them to the Chairperson of the IRB. The IRB application form is accessible through the SU website – Office of Research & Development site's "Forms and Policies" section.

2. They should indicate which of the above categories applies to their research. Approval requires the consent of the chairperson and one other member of the IRB. If approval is granted, the Chairperson shall so designate, record, and give notice to the principal investigator within one (1) month. The investigator may not initiate the project until approval is granted.

3. Prior to any changes made in the approved protocol, a new or revised IRB application must be submitted to the IRB for their recommendation.

4. Prior to implementing any changes, a new or revised IRB application must be approved by the IRB.

Full Board Review Status

A. Criteria for Full Board Approval

All research projects not meeting the criteria for Exempted or Expedited Review must be reviewed by the full IRB. This is required when research involves more than minimal risk or the subjects come from special populations such as those with limited civil freedom, children (unless exempt from review), or subjects with limited mental capacity. Principal investigators should be advised that additional protections are mandated for other at-risk groups.

1. Activities directed towards pregnant women (45 CFR 46-207)

2. Activities directed towards fetuses (45 CFR 46.208-210)

3. Activities directed towards prisoners as subjects (45 CFR 46.301)

Should your research include any of these groups, please read the listed CFR references before preparing and submitting your research application.

B. Procedures for Obtaining Full Board Review

1. Principal investigators who believe their projects require a Full Board Review should complete two (2) copies of the IRB application and submit them to the chairperson of the IRB.

2. Approval requires the consent of a majority of the Board. If approval is granted, the chairperson shall so designate, record, and give notice to the principal investigator within one (1) month and the investigator may not initiate the project until approval is granted.

3. If the investigator needs to make any change in the approved protocol (e.g., change procedures), a new IRB application must be submitted to the IRB for review.

4. Prior to implementing any changes, a new IRB application must be approved by the IRB.

Research for Instructional Purposes

A. Research designed for the purpose of classroom instruction and not designed to contribute to generalized knowledge does not require IRB review, if (1) the instructor educates the class about human subjects' rights (e.g., informed consent, confidentiality, risks vs. benefit, use of at-risk subjects—children, pregnant women, prisoners, etc., and (2) the instructor assumes ethical and professional responsibility for monitoring the progress of each research project in his or her class.

B. Should an instructor choose not to assume the overall responsibility for class projects, then each student must submit an application to the IRB as outlined.

C. The classroom instructor must send a memo to the chairperson of the IRB, indicating that class projects are on-going and the conditions outlined in this paragraph will be followed.

D. Research primarily for instructional purposes does not imply that students are exempt from following human subjects protection guidelines. They must, in fact, observe ethical principles as closely as others.

Informed Consent

The principle of informed consent is central to ethical treatment of human subjects. Under most circumstances the principle of informed consent requires that (1) the subject's participation in the research be entirely voluntary, and (2) subjects be given sufficient information about the research so that they can make a decision as to whether or not they wish to participate.

Written informed consent should be obtained from each subject who is legally, mentally, and physically able to provide it. Failure of a subject to express an unwillingness to participate does not constitute consent to participate in the project.

For subjects not able to provide informed consent themselves, written informed consent must be obtained from others (e.g., parents, guardians).

If the principal investigator requests a waiver of informed consent, the project is automatically excluded from Exempt status and must receive an Expedited or Full Board Review. The researcher must receive permission from the IRB or the chairperson and one other member (in the case of an Expedited review), if informed consent process is altered or waived.

The IRB may approve a consent procedure which alters some or all of the elements of informed consent or may waive the requirements of written informed consent altogether under the following circumstances:

1. the research involves no more than minimal risk to the subjects, or

2. the waiver or alteration will not adversely affect the rights and welfare of the subjects, or

3. the research could not be practically carried out without the waiver or alteration, or

4. in cases where the only record linking the subject and the research would be the consent document and the principle risk would be the potential harm resulting from a breach of confidentiality (in these cases, the subjects will be asked whether they want documentation linking themselves with the research; consent forms can be collected separately from the rest of the data), or

5. in cases where the research presents only minimal risk of harm to the subjects and involves no procedures for which written consent is normally required outside the research context.

   In cases where signed, written informed consent is waived, the IRB may require the investigator to provide the subjects with a written statement regarding the purpose of the research.

Written Consent

A copy of the consent form must be included with the IRB application. Essential elements of a written consent form are provided below. A written consent form should include the elements below that are applicable, and it should relate to a specific study. It should not be a "standard" form. It must be written in simple language so as to be easily understood by persons with no medical or scientific background. Potential subjects must be given all information that might reasonably be expected to influence their willingness to participate. Provide two (2) copies of the consent form, one for the subject, parent, or guardian to sign and return, and the other for him/her to keep.

A. Elements of the Consent Form

   A consent form must include the following:

   1. A simple, descriptive title of the research project (optional);
   2. Name and telephone number of the principal investigator or faculty advisor;

   3. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of

the procedures to be followed, and identification of any procedures which are experimental;

4. A description of any reasonable foreseeable risks or discomforts to the subject;

5. A description of any benefits to the subject or to others which may reasonably be expected from the research;

6. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

7. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

8. For research involving more than minimal risk, an explanation as to whether any compensation or medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

9. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;

10. A statement that subjects may contact the Institutional Review Board at any time during this study, if they feel their rights have been violated;

11. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which he or she is otherwise entitled;

12. Signature of the subject indicating consent (signature of parent or legal guardian for subjects who cannot legally represent themselves);

13. When appropriate, a simply worded consent form for children who can read and write should be prepared for their signature (this is in addition to the consent form signed by the parent or guardian; see following section for additional information about research with children).

B. Additional Elements of Informed Consent

When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject;
6. The approximate number of subjects involved in the study.

NOTE: SU recommends that if video or audio taping is part of the data gathering procedure, an additional statement be added to the effect: "This information may be used for multiple purposes (i.e., instruction) and will be archived for future use."

C. Children as Research Subjects

1. Children (under 18 years in age) are permitted to be research subjects if:
    a. there is no greater than minimal risk, or
    b. an intervention or procedure holds out the prospect of direct benefit for the individual subject, or a monitoring procedure is likely to contribute to the subject's well-being, or
    c. there is only a minor increase over minimal risk and the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the subject's disorder or condition, and
    d. the intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social or educational situations.

2. Consent by Parents or Guardians
    a. According to the federal regulations on the Protection of Subjects, for research falling under categories 1a and 1b above, the permission of one parent is sufficient.

    b. Permission from both parents is required for category 1c above unless one parent is deceased, unknown, incompetent or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

    c. The IRB requires parental consent to be written.

D. Children's Assent

In addition to parental permission, federal regulations require, in most instances, that a child who is sufficiently mature to comprehend his/her participation in the research project be offered the opportunity to give "Assent," which means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. Under some circumstances, written assent may be appropriate but, generally, verbal assent will be sufficient. When a written form is used, it should contain a simple explanation of the research project, including possible benefits, risks and safeguards. A copy of the assent form should be included in the proposal. There is no requirement of securing a child's assent if the research holds out a prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of research.

Investigator Responsibilities

A. General Responsibilities

The IRB requires that all investigators, whether faculty members, staff members, graduate students or undergraduate students, comply with both internal and federal regulations regarding the protection of human subjects and the appropriate administration of protocol activities. Researchers, in turn, have the responsibility of staying abreast of policies to remain within compliance. Failure to do so will result in the investigator losing his or her capability to perform as the individual responsible for the administration of the research protocol.

B. Specific Responsibilities
    1. Investigators are responsible for completing the CITI Program training prior to initiating a new protocol or renewing an existing one.

2. Investigators are responsible for ensuring that all research involving human subjects is submitted to and approved by the IRB prior to initiation of the research. Investigators have the primary responsibility for protecting the rights and welfare of human research subjects. In addition, they are expected to be knowledgeable about the requirements of the federal regulations and institutional policies and procedures for the protection of human subjects.

3. Investigators are responsible for complying with all IRB policies, decisions, conditions, and requirements. Investigators are responsible for ensuring that the research is implemented as specified in the approved IRB protocol.

4. Investigators are responsible for obtaining and documenting informed consent for each participant and providing a copy of the IRB-approved consent form to each subject, unless the IRB has specifically waived this requirement.

5. Investigators are responsible for ensuring that assent from research participants who are minors (18 years of age and under) is obtained and documented.

6. Investigators are responsible for reporting progress of approved research to the IRB, as often as and in the manner prescribed by the IRB, but no less than once per year.

7. Investigators are responsible for promptly submitting to the IRB any modifications to a protocol or consent form of an approved protocol.

8. Investigators are responsible for promptly reporting any injuries, adverse events, or other unanticipated problems involving risks to participants.

9. Investigators are responsible for maintaining a protocol file that includes all correspondence between the IRB and principal investigator and retaining copies of signed consent forms.

Protocol Files

1. The principal investigator must maintain a protocol file, which must include:
    a. All correspondence between the investigator and the IRB as well as any communications regarding the study from a sponsor.

    b. Copies of the signed Consent Form obtained from all participants or information as to where these documents can be found.

c. Any data derived from the study.

d. Progress reports.

e. Reports of all adverse incidents and any follow-up to adverse incidents.

f. Current contact point for the investigator (address and telephone number) should the investigator no longer be associated with SU.

2. This file will act as the investigator's documentation regarding the proper performance of the study. Investigators should be aware that this file will be randomly audited on a semi-annual basis by the IRB. The purpose of this audit is to provide internal procedural monitoring to ensure compliance with federal human subject protection regulations. Additionally, it provides a cooperative forum to educate the investigator in correcting problems and to solicit suggestions in improving the IRB process.

3. The investigator must maintain the protocol file for at least five (5) years past completion of the research activity for adult subjects and, for minor subjects, at least three (3) years after reaching the age of 18, whichever is longer. The file must contain copies of data files, consent forms, progress reports and other items used in the course of the investigator's research while employed at SU. If an investigator leaves SU prior to this five (5)-year period, he/she must notify the IRB in writing of the individual taking over the responsibility for these records (e.g., Department Chair, School Dean, Human Protections Office). All files must be kept in a secure location.

Non-Compliance

A. Federal Requirements

1. As stated in the federal regulations (45 CFR 46.113), all protocol deviations and/or instances of non-compliance with IRB regulations must be reported to the IRB by the principal investigator as soon as the violations are discovered. The IRB has the authority to suspend or terminate approval of research not conducted in accordance with the IRB's requirements or that research has been associated with unexpected serious harm to subjects. The IRB also has the authority to "sanction", "suspend", or "terminate" approval if there has been serious or

continuing non-compliance with the policies, requirements or determinations of the IRB.

2. Investigators not in compliance with IRB procedures will not be able to process new protocols or renew current projects until all concerns have been addressed and the investigator sends a letter to the IRB Chair acknowledging the error that was made.

B. Minor Protocol Deviations

1. Investigators are responsible for conducting human research with participants in compliance with federal regulations and SU policies and procedures. Failure to comply with these administrative regulations may result in the loss of an individual investigator's ability to conduct research but can also affect the ability of all others at SU to perform human participant research. Non-compliance with regulations may be seen as protocol deviations.

2. Deviations generally do not have substantive effects on the safety or well-being of research participants; do not affect the value of the data collected (meaning the violation does not confound the scientific analysis of the results); do not result from willful or knowing misconduct on the part of the investigator(s); and do not violate any ethical principles. Deviations are often caused by an investigator failing to communicate effectively with the IRB. When such instances are discovered, the IRB will act promptly to halt the research to ensure remedial action regarding compliance with federal and institutional human participant protection requirements.

C. Common deviations in investigator compliance include:

1. unreported changes in the IRB-approved protocol or consent documents.

2. misuse or non-use of the IRB-approved informed consent documents.

3. lapse in obtaining approval for continuing review.

4. failure to obtain IRB approval prior to starting research activities.

5. failure to file protocol modifications.

Deviation Reporting Procedure

1. Investigators can almost always avoid protocol deviations by being aware of the IRB requirements and following the approved protocol. If a protocol deviation does occur, an investigator must submit report to the IRB for review immediately upon discovery. This report will serve as the documentation for modifying the particular protocol; investigators must await IRB approval before implementing anticipated changes or modifications.

2. Following the review of the report, the IRB chair will notify the investigator in writing of the need to meet to discuss the deviation and develop a plan to avoid such actions in the future. The results of the meeting will determine what must be done (if anything) to correct the conditions that lead to the deviation and what (if anything) must be communicated to the research participants. Participant enrollment may be suspended pending resolution of the problem or concern. The IRB chair will present a summary of the deviation, process, facts, and conclusions at the next scheduled convened IRB meeting.

D. Protocol Violations
    1. Protocol violations emerge when there is a variance in a research study between the protocol that has been reviewed and approved by the IRB and the actual activities being performed. Reports may come from a variety of sources: participants, community members, research staff, etc.

    2. Reporting of violations will be made, in writing, to the IRB chair; all reports will be held in the strictest of confidence and discussed within the confines of the fact-finding committee.

    3. Examples of protocol violations:
        a. Modifications of protocols are unapproved by the IRB that caused substantive harm to research participants
        b. Modifications of protocols that cause damage to the scientific integrity of the data collected
        c. Modifications of protocols which result in willful or knowing misconduct on the part of the investigator
        d. Modifications of protocols that impact on ethical principles

E. Violation Investigation Procedure
    1. Incidents of alleged or known protocol violations may be investigated by the IRB

via the following steps:

a. The IRB chair will create a fact finding committee, composed of:
    1) the IRB chair
    2) the designated Human Research Protections Administrator
    3) two or more representatives from the PI's department or discipline, and
    4) a representative from the SU legal counsel.

b. This committee will analyze all information gathered regarding the protocol violation and compare it to the approved protocol. When necessary, the committee will consult with experts in the specific discipline of research in order to make definitive, unbiased and educated decisions regarding the violation. A conclusion will then be made regarding the seriousness of the violation.
c. If the hearing committee finds any of the protocol violations criteria noted above, the IRB chair will immediately suspend the protocol. The IRB chair may suspend the protocol in advance of the hearing if, in the chair's assessment, the conditions in 45 CFR 46.113 have not been met and warrant an emergency protocol suspension). If suspension of the protocol results from harm to the enrolled research participants, the IRB chair will request that the PI's department chair assign PI duties to another qualified person. In this situation, the official action will be the suspension of the investigator (45 CFR 46.109[d]).

2. Depending on the nature or the seriousness of the violation, the committee may elect to direct the IRB to audit all protocols that involve the investigator in question. If the findings of the hearing committee support research misconduct, the Executive Vice President for Academic Affairs will be notified. A summary of the violation, process, facts, and conclusions will be presented at the next scheduled IRB meeting. The IRB chair will notify the investigator in writing with copies to the PI's department chair, the appropriate dean, and the Office for Human Research Protections. If an investigator disagrees with the findings or requirements of the committee, investigators have the right to appeal the committee's decision to the Academic Dean.

Protocol Audits

A. Federal Regulations

1. The Human Research Protection Office makes arrangements to meet personally with the investigator and/or research staff to examine the investigator's protocol file. Investigators should plan to allow for at least one (1) hour for the Human Research Protections Office to conduct the review; while the investigator's presence is not required, it will be helpful to be present to answer any questions. Student investigators and faculty advisors should meet prior to the review to make arrangements for a meeting time and access to the protocol files.

B. SU Audit Procedure

1. The Human Research Protections Office will examine the following items in the researcher's protocol file:
    a. the use and retention of an IRB-approved consent form for all participants recruited for the research. A comparison will be made between the number of consent forms signed by participants that are maintained in the researcher's protocol file with the actual number of participants recruited for the research;
    b. the use of the IRB-approved measures, surveys, questionnaires, etc. A comparison will be made of the forms used in the study with those retained in the Human Research Protections Office protocol file;
    c. copies of protocol correspondence between the investigator and the IRB, including a copy of the investigator's IRB training certificate;
    d. reports of all adverse incidents and any follow-up to adverse incidents; and
    e. the investigator's data storage medium will be examined to determine if the appropriate measures are undertaken to ensure confidentiality and minimize risk to participants. Applicable items to be reviewed include the use of a secured location (lock and key system), an updated firewall or virus protection program and secure data tracking systems.

2. Maintaining confidentiality of data sources is important while the study is active. Data should be stored in a secured location and identified by code numbers only. A master list must be kept in a separate location from the data, with only the investigator and his/her designee responsible for access to the data.

3. If audio and video tapes have been used in the study, the recommended length of time for keeping tapes is three (3) years beyond the completion of the study. However, data from audio or video tapes should be transcribed as soon as possible; once accomplished, these tapes should be erased or destroyed.

4. Signed consent forms and other relevant documents must be maintained and made available for review for at least five (5) years past completion of the research activity for adult subjects and, for minor subjects, at least three (3) years after reaching the age of 18, whichever is longer.

5. The results of the audit must be kept in the investigator's protocol file.

Office of Human Research Protections

A. Human Research Protections Officer

1. The SU Human Research Protections Office will be a component of the Office of Institutional Research and Assessment.

2. The Executive Vice President for Academic Affairs will designate the Human Research Protections Officer.

3. The Human Research Protections Officer has the responsibility to implement procedures to fulfill the responsibilities of the Office of Human Research Protections. **Investigators have the ultimate responsibility to protect human subjects.**

B. Responsibilities of the Office of Human Research Protections

1. Records Maintenance
    a. The office will maintain a permanent protocol file of all IRB protocols.
    b. The office will maintain a database of all research protocols that proposes to use human participants. Minimally, the database will include the investigator's name, the title of the proposed research, and current IRB status.

2. The office will maintain all IRB records relevant to protocol deviations or violations.

3. Protocol Audit
    a. The office is responsible for the semi-annual internal review (i.e., audit) to ensure that protocol activity remains within compliance with the approved Federal-wide Assurance.
    b. Protocol violations identified by the audit will be reported to the Executive Vice President for Academic Affairs.

Bibliography

Protection of Human Subjects, 1983, Code of Federal Regulations, Title 45, Part 46 (45 CFR 46), OPRR Reports, p. 19.

The Belmont Report, 1979, OPRR Reports, p. 8.
The Common Federal Rule, 1991, Federal Register, p. 28012-28018.

4.15 RESPONDING TO ALLEGATIONS OF SCIENTIFIC MISCONDUCT

Definitions[1]

A. Allegation means any written or oral statement or other indication of possible scientific misconduct made to an institutional official.

B. Deciding Official means the institutional official who makes final determinations on allegations of scientific misconduct and any responsive institutional actions.

C. Employee means, for the purpose of these instructions only, any person paid by, under the control of, or affiliated with the institution, including but not limited to scientists, physicians, trainees, students, fellows, technicians, nurses, support staff, and guest researchers

D. Good faith allegation means an allegation made with the honest belief that scientific misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation.

E. Inquiry means information-gathering and initial fact-finding to determine whether an allegation or apparent instance of scientific misconduct warrants an investigation.

F. Institutional counsel means legal counsel who represents the institution during the scientific misconduct inquiry and investigation and who is responsible for advising the Research Integrity Officer, the inquiry and investigation committees, and the Deciding Official on relevant legal issues. The institutional counsel does not represent the respondent, the whistleblower, or any other person participating during the inquiry, investigation, or any follow-up action, except the institutional officials responsible for managing or conducting the institutional scientific misconduct process as part of their official duties.

G. Investigation means the formal examination and evaluation of all relevant facts to determine if scientific misconduct has occurred and, if so, to determine the responsible person and the seriousness of the misconduct.

H. ORI means the Office of Research Integrity, the office within the U.S. Department of Health and Human Services (DHHS) that is responsible for the scientific misconduct and research integrity activities of the U.S. Public Health Service.

I. PHS means the U.S. Public Health Service, an operating component of the U.S. Department of Health and Human Services.

J. PHS regulation means the Public Health Service regulation establishing standards for institutional inquiries and investigations into allegations of scientific misconduct, which is set forth at 42 C.F.R. Part 50, Subpart A, entitled "Responsibility of PHS Awardee and Applicant Institutions for Dealing With and Reporting Possible Misconduct in Science."

K. PHS support means Public Health Service grants, contracts, or cooperative agreements, or applications therefore.

L. Research Integrity Officer means the institutional official responsible for assessing allegations of scientific misconduct and determining when such allegations warrant inquiries and for overseeing any inquiries and investigations.

M. Research record means any data, document, computer file, computer diskette, or any other written or non-written account or object that reasonably may be expected to provide evidence or information regarding the proposed, conducted, or reported research that constitutes the subject of an allegation of scientific misconduct. A research record includes, but is not limited to, grant or contract applications, whether funded or unfunded; grant or contract progress and other reports; laboratory notebooks; notes; correspondence; videos; photographs; X-ray film; slides; biological materials; computer files and printouts; manuscripts and publications; equipment use logs; laboratory procurement records; animal facility records; human and animal subject protocols; consent forms; medical charts; and patient research files.

N. Respondent means the person against whom an allegation of scientific misconduct is directed or the person who is the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

O. Retaliation[2] means any action that adversely affects the employment or other status of an individual that is taken by an institution or an employee because the individual has, in good faith, made an allegation of scientific misconduct or of inadequate institutional response thereto, or has cooperated in good faith with an investigation of such allegation.

P. Scientific misconduct or misconduct in science means fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community for proposing, conducting, or reporting

research. It does not include honest error or honest differences in interpretations or judgments of data.

Q. Whistleblower means a person who makes an allegation of scientific misconduct.

General Procedures and Principles

A. Responsibility to Report Misconduct. Institutional employees who receive or learn of an allegation of scientific misconduct will immediately report the allegation to the Research Integrity Officer for appropriate action. The Research Integrity Officer will promptly engage in an assessment of the allegation to determine whether it falls within the definition of scientific misconduct, involves PHS support, and provides sufficient information to proceed with an inquiry.

B. Protecting the Whistleblower[3]. Institutional employees who receive or learn of an allegation of scientific misconduct will treat the whistleblower with fairness and respect and, when the allegation has been made in good faith, will take reasonable steps to protect the position and reputation of the whistleblower and other individuals who cooperate with the institution against retaliation. Employees will immediately report any alleged or apparent retaliation to the Research Integrity Officer.

C. Protecting the Respondent[4]. Institutional employees who receive or learn of an allegation of scientific misconduct will treat the respondent with fairness and respect and will take reasonable steps to ensure that the procedural safeguards in the PHS regulation, 42 C.F.R. Part 50, Subpart A, and these procedures are followed. Employees will report significant deviations from these instructions to the Research Integrity Officer. The Research Integrity Officer will report any allegation not made in good faith to the Deciding Official for appropriate action.

D. Confidentiality[5]. Institutional employees who make, receive, or learn of an allegation of scientific misconduct will protect, to the maximum extent possible, the confidentiality of information regarding the whistleblower, the respondent, and other affected individuals. The Research Integrity Officer may establish reasonable conditions to ensure the confidentiality of such information.

E. Responding to Allegations. In responding to allegations of scientific misconduct, the Research Integrity Officer and any other institutional official with an assigned responsibility for handling such allegations will make diligent efforts to ensure that the following functions are performed.

1. Any allegation assessment, inquiry, or investigation is conducted in a timely, objective, thorough, and competent manner.[6]

2. Reasonable precautions are taken to avoid bias and real or apparent conflicts of interest on the part of those involved in conducting the inquiry or investigation.[7]

3. Immediate notification is provided to ORI if [8]:
    a. there is an immediate health hazard involved;
    b. there is an immediate need to protect Federal funds or equipment;
    c. there is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;
    d. it is probable that the alleged incident is going to be reported publicly;
    e. the allegation involves a public health sensitive issue, e.g., a clinical trial;
    f. there is a reasonable indication of a possible Federal criminal violation. In this instance, the institution must inform ORI within 24 hours of obtaining that information.

4. Interim administrative actions are taken, as appropriate, to protect Federal funds and the public health, and to ensure that the purposes of the Federal financial assistance are carried out.[9]

F. Employee Cooperation[10]
Institutional employees will cooperate with the Research Integrity Officer and other institutional officials in the review of allegations and the conduct of inquiries and investigations. Employees have an obligation to provide relevant evidence to the Research Integrity Officer or other institutional officials on misconduct allegations. Further, employees will cooperate with ORI in its conduct of inquiries and investigations, its oversight of institutional inquiries and investigations, and any follow up actions.

G. Evidentiary Standards[11]
The following evidentiary standards apply to findings of scientific misconduct made under the PHS regulation.
    1. Burden of Proof. The burden of proof for making a finding of scientific misconduct is on the institution. [Note: If ORI adopts the institutional finding of scientific misconduct or makes an ORI finding, the burden of proof is on ORI for purposes of its finding and administrative actions.]

2. Standard of Proof. Any institutional or ORI finding of scientific misconduct will be established by a preponderance of the evidence. This means that the evidence shows that it is more likely than not that the respondent committed scientific misconduct.

H. Completion of Process

The Research Integrity Officer is responsible for ensuring that the inquiry/investigation process and all other steps required by this instruction and the PHS regulation are completed even in those cases where the respondent leaves the institution after allegations are made.

I. Early Termination[12]

If the institution plans to terminate an inquiry or investigation prior to completion of all the steps required by the PHS regulation, the Research Integrity Officer will notify ORI of the planned termination and the reasons therefore. ORI will review the information provided and advise the institution whether further investigation should be undertaken.

J. Referral of Non-Scientific Misconduct Issues

When the institution's review of the allegation identifies non-scientific misconduct issues, the Research Integrity Officer should refer these matters to the proper institutional or Federal office for action. Issues requiring referral are described below.

1. HHS Criminal Violations[13]

   Potential violation of criminal law under HHS grants and contracts should be referred to the Office of Inspector General, HHS-OIG Hot line, P.O. Box 17303, Baltimore, MD 21203-7303, telephone (800) 368-5779. If the possible criminal violation is identical to the alleged scientific misconduct (e.g., alleged false statements in a PHS grant application), the criminal charge should be reported to ORI. ORI will then refer it to OIG.

2. Violation of Human and Animal Subject Regulations

   Potential violations of human subject regulations should be referred to the Office of Human Research Protections, Department of Health and Human Services, 6100 Executive Boulevard, Suite 3B01, Rockville, MD 20892-7507. Phone: 301-496-7005. Email: ohrp@osophs.dhhs.gov.

   Potential violations of animal subject regulations should be referred to the Office of Laboratory Animal Welfare, National Institutes of Health, 6705 Rockledge Drive, RKL1, Suite 1050, MSC 7982, Bethesda, MD 208927982, Phone: 301-402-5913.

3. Violation of FDA Regulations
   Potential violations of Food and Drug Administration regulated research requirements should be referred to the FDA Office of Regulatory Affairs, Division of Compliance Policy, Bioresearch Program Coordination, 5600 Fishers Lane, HFC-230 TWBK 715, Rockville, MD 20857, telephone (301) 827-0420.

4. Fiscal Irregularities
   Potential violations of cost principles or other fiscal irregularities should be referred as follows:
   a. For all NIH Agencies--Office of Management Assessment, NIH, Building 31, Room 1B05, Bethesda, MD 20892, telephone (301) 496-1361.
   b. For all other PHS Agencies--PHS Office of Grants and Contracts, 5600 Fishers Lane, Room 17A39, Rockville, MD 20857, telephone (301) 443-6630.

   If there are any questions regarding the proper referral of non-scientific misconduct issues, the Research Integrity Officer may call the ORI Division of Research Investigations at (301) 443- 5330 to obtain advice.

K. Requirements for Reporting to ORI

1. An institution's decision to initiate an investigation must be reported in writing to the Director, ORI, on or before the date the investigation begins.[14] At a minimum, the notification should include the name of the person(s) against whom the allegations have been made, the general nature of the allegation as it relates to the PHS definition of scientific misconduct, and the PHS applications or grant number(s) involved.[15] ORI must also be notified of the final outcome of the investigation and must be provided with a copy of the investigation report.[16] Any significant variations from the provisions of the institutional policies and procedures should be explained in any reports submitted to ORI.

2. If an institution plans to terminate an inquiry or investigation for any reason without completing all relevant requirements of the PHS regulation, the Research Integrity Officer will submit a report of the planned termination to ORI, including a description of the reasons for the proposed termination.[17]

3. If the institution determines that it will not be able to complete the investigation in 120 days, the Research Integrity Officer will submit to ORI a written request for an extension that explains the delay, reports on the progress to date, estimates the

date of completion of the report, and describes other necessary steps to be taken. If the request is granted, the Research Integrity Officer will file periodic progress reports as requested by the ORI.[18]

4. When PHS funding or applications for funding are involved and an admission of scientific misconduct is made, the Research Integrity Officer will contact ORI for consultation and advice. Normally, the individual making the admission will be asked to sign a statement attesting to the occurrence and extent of misconduct. When the case involves PHS funds, the institution cannot accept an admission of scientific misconduct as a basis for closing a case or not undertaking an investigation without prior approval from ORI.[19]

5. The Research Integrity Officer will notify ORI at any stage of the inquiry or investigation if:
    a. there is an immediate health hazard involved;[20]

    b. there is an immediate need to protect Federal funds or equipment;[21]

    c. there is an immediate need to protect the interests of the person(s) making the allegations or of the individual(s) who is the subject of the allegations as well as his/her co-investigators and associates, if any;[22]

    d. it is probable that the alleged incident is going to be reported publicly;[23] or

    e. the allegation involves a public health sensitive issue, e.g., a clinical trial;

    f. there is a reasonable indication of possible criminal violation. In this instance, the institution must inform ORI within 24 hours of obtaining that information.[24]

Preliminary Assessment of Allegations

A. Allegation Assessment

Upon receiving an allegation of scientific misconduct, the Research Integrity Officer will immediately assess the allegation to determine whether there is sufficient evidence to warrant an inquiry, whether PHS support or PHS applications for funding are involved, and whether the allegation falls under the PHS definition of scientific misconduct.

1. PHS Support

Allegations involving research supported by PHS-funded grants, contracts, or cooperative agreements, or applications for PHS funding connote PHS support. If the allegation does not involve PHS support, it should be handled under the institution's own definition of scientific misconduct and procedures without regard to the PHS regulation at 42 C.F.R. Part 50, Subpart A.

2. PHS Definition

The allegation should be carefully reviewed to determine whether it potentially constitutes fabrication, falsification, plagiarism, or other serious deviation from commonly accepted practices for proposing, conducting, or reporting research. In case of doubt, the Research Integrity Officer should consult with the institutional counsel or ORI on whether the allegation falls within the PHS definition of scientific misconduct.

3. Sufficient evidence to proceed

There is not always sufficient evidence or information to permit further inquiry into the allegation. For example, an allegation that a scientist's work should be subjected to general examination for possible misconduct is not sufficiently substantial or specific to initiate an inquiry. In case of such a vague allegation, an effort should be made to obtain more information before initiating an inquiry. This information may be sought from any reasonable source, including the whistleblower, if known.

B. Referral of Other Issues

Regardless of whether it is determined that a scientific misconduct inquiry is warranted, if the allegation involves PHS support and concerns possible failure to protect human or animal subjects, financial irregularities, or criminal activity, the allegation should be referred to the appropriate PHS or DHHS office. See section III-J.

Conducting the Inquiry[25]

A. Initiation and Purpose of the Inquiry[26]

Following the preliminary assessment, if the Research Integrity Officer determines that the allegation provides sufficient information to allow specific follow-up, involves PHS support, and falls under the PHS definition of scientific misconduct, he or she will immediately initiate the inquiry process. In initiating the inquiry, the Research Integrity Officer should identify clearly the original allegation and any related issues that should be evaluated. The purpose of the inquiry is to make a preliminary evaluation of the

available evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation. The purpose of the inquiry is not to reach a final conclusion about whether misconduct definitely occurred or who was responsible. The findings of the inquiry must be set forth in an inquiry report.

B. First Steps If an Inquiry Is Necessary
As soon as practicable after the Research Integrity Officer determines that an inquiry is required, he or she will:

1. secure the relevant research records;

2. notify the President of the Institution, Academic Dean, School Dean, Department Chair, institutional counsel, the respondent, and ORI (if the request to open the inquiry originated from ORI);

3. appoint and charge the inquiry committee; and

4. notify ORI if any of the conditions listed in section III.E.3 of these procedures are present. The Research Integrity Officer or institutional counsel may consult with ORI at any time regarding appropriate procedures to be followed.

C. Sequestration of the Research Records
1. Immediate Sequestration
If the relevant research records have not been obtained at the assessment stage, the Research Integrity Officer will immediately locate, collect, inventory, and secure them to prevent the loss, alteration, or fraudulent creation of records.

2. Institutional Access
Research records produced under PHS grants and cooperative agreements are the property of the institution, and employees cannot interfere with the institution's right of access to them. Under contracts, certain research records may belong to PHS, but the institution will be provided access to contract records in the custody of the institution for purposes of reviewing misconduct allegations.

3. Original Records
The documents and materials to be sequestered will include all the original items (or copies if originals cannot be located) that may be relevant to the allegations.

These include, but are not limited to, research records as defined in section II.N of this document.

4. Sequestration of the Records from the Respondent
   The Research Integrity Officer should notify the respondent that an inquiry is being initiated simultaneously with the sequestration so that the respondent can assist with location and identification of the research records. The Research Integrity Officer should obtain the assistance of the respondent's supervisor and institutional counsel in this process, as necessary. If the respondent is not available, sequestration may begin in the respondent's absence. The respondent should not be notified in advance of the sequestration of research records to prevent questions being raised later regarding missing documents or materials and to prevent accusations against the respondent of tampering with or fabricating data or materials after the notification. In addition to securing records under the control of the respondent, the Research Integrity Officer may need to sequester records from other individuals, such as coauthors, collaborators, or whistleblowers. As soon as practicable, a copy of each sequestered record will be provided to the individual from whom the record is taken if requested.

5. Inventory of the Records
   A dated receipt should be signed by the sequestering official and the person from whom an item is collected, and a copy of the receipt should be given to the person from whom the record is taken. If it is not possible to prepare a complete inventory list at the time of collection, one should be prepared as soon as possible, and then a copy should be given to the person from whom the items were collected.

6. Security and Chain of Custody
   The Research Integrity Officer will lock records and materials in a secure place. The persons from whom items are collected may be provided with a copy of any item. Where feasible, that person will have access to his or her own original items under the direct and continuous supervision of an institutional official. This will ensure that a proper chain of custody is maintained and that the originals are kept intact and unmodified. Questions about maintaining the chain of custody of records should be referred to the institutional counsel.

D. Notification of the Respondent

1. Contents of Notification

   The Research Integrity Officer will notify the respondent in writing of the opening of the inquiry. The notification should identify the research project in question and the specific allegations, define scientific misconduct, identify the PHS funding involved, list the names of the members of the inquiry committee (if appointed) and experts (if any), explain the respondent's opportunity to challenge the appointment of a member of the committee or expert for bias or conflict of interest, to be assisted by counsel, to be interviewed, to present evidence to the committee, and to comment on the inquiry report; address the respondent's obligation as an employee of the institution to cooperate; describe the institution's policy on protecting the whistleblower against retaliation and the need to maintain the whistleblower's confidentiality during the inquiry and any subsequent proceedings.

2. Potential Respondents

   If no specific respondent has been identified at this stage of the process, the Research Integrity Officer, in consultation with the institutional counsel, will notify each potential respondent that an inquiry will be undertaken, e.g., each coauthor on a questioned article or each investigator on a questioned grant application.

E. Designation of an Official or a Committee to Conduct the Inquiry

   The Research Integrity Officer is responsible for conducting or designating others to conduct the inquiry.

1. Use of an Inquiry Committee

   In complex cases, the Research Integrity Officer will normally appoint a committee of three or more persons to conduct the inquiry, following the procedures set forth in section V.E.

2. Use of an Inquiry Official

   In cases in which the allegations and apparent evidence are straightforward, such as an allegation of plagiarism or simple falsification or an admission of misconduct by the respondent, the Research Integrity Officer may choose to conduct the inquiry directly or designate another qualified individual to do so. In such cases, the inquiry official will nevertheless obtain the necessary expert and technical advice to consider properly all scientific issues.

3. Inquiry Process
   The inquiry, whether conducted by a committee or an individual, will follow each procedural step set forth below.

F. Appointment of the Inquiry Committee
   If an inquiry committee is to be appointed, the Research Integrity Officer will use the following procedures:

   1. Committee Membership
      The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint the committee and committee chair within 10 days of the initiation of the inquiry. The inquiry committee should consist of at least three individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegation, interview the principals and key witnesses, and conduct the inquiry. These individuals may be scientists, subject matter experts, administrators, lawyers, or other qualified persons, and they may be from inside or outside of the institution.

   2. Experts
      The Research Integrity Officer, in consultation with the committee, will determine whether additional experts other than those appointed to the committee need to be consulted during the inquiry to provide special expertise to the committee regarding the analysis of specific evidence. In this case, the experts provide a strictly advisory function to the committee; they do not vote and generally do not interview witnesses. The experts chosen may be from inside or outside of the institution.

   3. Bias or Conflict of Interest
      The Research Integrity Officer will take reasonable steps to ensure that the members of the committee and experts have no bias or personal or professional conflict of interest with the respondent, whistleblower, or the case in question. In making this determination, the Research Integrity Officer will consider whether the individual (or any members of his or her immediate family):
         a. has any financial involvement with the respondent or whistleblower;
         b. has been a coauthor on a publication with the respondent or whistleblower;

c. has been a collaborator or co-investigator with the respondent or whistleblower;
d. has been a party to a scientific controversy with the respondent or whistleblower;
e. has a supervisory or mentor relationship with the respondent or whistleblower;
f. has a special relationship, such as a close personal friendship, kinship, or a physician/patient relationship with the respondent or whistleblower; or
g. falls within any other circumstance that might appear to compromise the individual's objectivity in reviewing the allegations.

4. Objection by Respondent
The Research Integrity Officer will notify the respondent of the proposed committee membership within 10 days. If the respondent submits a written objection to any appointed member of the inquiry committee or expert based on bias or conflict of interest within 5 days, the Research Integrity Officer will immediately determine whether to replace the challenged member or expert with a qualified substitute.

5. Confidentiality
Members of the committee and experts will agree in writing to observe the confidentiality of the proceeding and any information or documents reviewed as part of the inquiry. Outside of the official proceedings of the committee, they may not discuss the proceedings with the respondent whistleblower, witnesses, or anyone not authorized by the Research Integrity Officer to have knowledge of the inquiry.

6. Provision of Assistance
The Research Integrity Officer, in consultation with the institutional counsel, will provide staff assistance and guidance to the committee and the experts on the procedures for conducting and completing the inquiry, including procedures for maintaining confidentiality, conducting interviews, analyzing data, and preparing the inquiry report.

G. Charge to the Committee and the First Meeting

The Research Integrity Officer will prepare a charge for the inquiry committee that describes the allegations and any related issues identified during the allegation assessment and states that the purpose of the inquiry is to make a preliminary evaluation of the evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether there is sufficient evidence of possible scientific misconduct to warrant an investigation, as required by the PHS regulation. The purpose is not to determine whether scientific misconduct definitely occurred or who was responsible.

At the committee's first meeting, the Research Integrity Officer will review the charge with the committee, discuss the allegations, any related issues, and the appropriate procedures for conducting the inquiry, assist the committee with organizing plans for the inquiry, and answer any questions raised by the committee.

The Research Integrity Officer and institutional counsel will be present or available throughout the inquiry to advise the committee as needed.

H. General Approaches to Conducting the Inquiry

During the inquiry, the committee will take the following steps:

1. Avoid Bias or Conflict of Interest

   All necessary steps must be taken to avoid bias or conflict of interest between the committee and experts and the respondent, whistleblower, and witnesses.

2. Refer Other Issues

   The Research Integrity Officer must be advised of any necessary interim actions to protect the research funds, human or animal subjects, or other steps required by regulation or policy. See section III.E.3 and III.J.

I. General Approaches to Conducting an Interview

1. Purpose of the Interview

   The purpose of an interview at the inquiry stage is to allow each respondent, whistleblower, or witness to tell his or her side of the story. The committee should not attempt to speculate about what happened or might have happened or put words in the witnesses' mouths. Also, the committee should not disclose information obtained from others interviewed unless this is necessary and can be done without identifying the source of the information.

2. Issues to Cover
   Before an interview, the committee should provide each witness with a summary of the matters or issues intended to be covered at the interview.

   If the committee raises additional matters, the witness should be given an opportunity to supplement the record in writing or in another interview.

   The witness should be informed that his or her cooperation and truthful answers are expected.

3. Confrontation
   Witnesses should not be told at this stage whether other testimony conflicts with theirs, although questions may be asked for purposes of clarifying the testimony. Avoid leading questions such as, "You must have made a mistake and thought it was actually this way, right?"

4. Using Experts
   The committee may request that experts attend or participate in interviews to assist in its evaluation of the allegations and related issues. If the committee determines that such participation is not appropriate, it may ask an expert to prepare questions for the committee to use at the interview. Any expert retained to assist the committee may read the transcripts or summaries of the interviews.

5. Transcribing Interviews
   Interviews with the respondent will be transcribed or recorded. Interviews with anyone else will be summarized, tape-recorded, or transcribed. A transcript or summary of the interview will be provided to each witness for review and correction of errors. Witnesses may add comments or information. Changes to the transcript or summary will be made only to correct factual errors.

6. Confidentiality of Interviews
   Witnesses should be advised that the proceedings are confidential and that they should not discuss the inquiry or their interview with anyone else other than their counsel or adviser.

7. Access to Counsel
   Witnesses may be accompanied and advised by legal counsel or by a non-legal adviser who is not a principal or witness in the case. However, the counsel or

adviser may only advise the witness and may not participate directly in the interview. Witnesses will respond directly to the interview questions.

8. Order of Interviews
   The inquiry committee should interview, if possible, the whistleblower, key witnesses, and the respondent, in that order. Witnesses should be asked to provide, in advance if possible, any relevant evidence including their own notes, manuscripts, research records, or other documents that were not sequestered previously but are relevant to the allegation.

9. Interviewing the Whistleblower
   In interviewing the whistleblower, the inquiry committee should attempt to obtain as much additional evidence regarding the substance of the allegation as possible and to determine the whistleblower's view of the significance and impact of the alleged misconduct. However, it is not the whistleblower's responsibility to prove his or her allegations.

10. Interviewing the Respondent
    The respondent should be asked to provide his or her own response to the allegations, including any analysis of the primary data. If the respondent claims that an honest error or difference of scientific judgment occurred, he or she should provide any evidence to support that claim. If he or she requests, the respondent may make a closing statement at the end of the interview.

11. Recording Admissions
    If the respondent admits to the misconduct, the respondent should be asked immediately to sign a statement attesting to the occurrence and extent of the misconduct. Normally, an admission is a sufficient basis to proceed directly to an investigation. However, the admission may not be a sufficient basis for closing a case. Further investigation may be needed to determine the extent of the misconduct or to explore additional issues. If an admission is made, the Research Integrity Officer or institutional counsel may seek advice from ORI in determining whether there is a sufficient basis to close a case, after the admission is fully documented and all appropriate procedural steps are taken. If the case is closed, the report should be forwarded to the Deciding Official with recommendations for appropriate institutional sanctions and then submitted to ORI for review.

12. Committee Deliberations

    The inquiry committee will evaluate the evidence and testimony obtained during the inquiry. After consultation with the Research Integrity Officer and institutional counsel, the committee members will decide whether there is sufficient evidence of possible scientific misconduct to recommend further investigation. The scope of the inquiry does not include deciding whether misconduct occurred or conducting exhaustive interviews and analyses.

    Committee deliberations should never be held in the presence of the interviewee. During the interview, the committee members should not debate among themselves or with witnesses over possible scientific interpretations. These questions should be reserved for private discussions among the inquiry committee members and expert consultants.

The Inquiry Report[27]

A. Elements of the Inquiry Report

   A written inquiry report must be prepared that states the name and title of the committee members and experts, if any; the allegations; the PHS support; a summary of the inquiry process used; a list of the research records reviewed; summaries of any interviews; a description of the evidence in sufficient detail to demonstrate whether an investigation is warranted; and the committee's determination as to whether an investigation is recommended and whether any other actions should be taken if an investigation is not recommended. Institutional counsel will review the report for legal sufficiency. All relevant dates should be included in the report.

B. Comments on the Draft Report by the Respondent and the Whistleblower28

   The Research Integrity Officer will provide the respondent with a copy of the draft inquiry report for comment and rebuttal and will provide the whistleblower, if he or she is identifiable, with those portions of the draft report that address the whistleblower's role and opinions in the investigation.

   1. Confidentiality

      The Research Integrity Officer may establish reasonable conditions for review to protect the confidentiality of the draft report.

   2. Receipt of Comments

      Within 10 calendar days of their receipt of the draft report, the whistleblower and respondent will provide their comments, if any, to the inquiry committee. Any comments that the whistleblower or respondent submits on the draft report will

become part of the final report and record.29 Based on the comments, the inquiry committee may revise the report as appropriate.

C. Inquiry Decision and Notification[30]

1. Decision by Deciding Official
   The Research Integrity Officer will transmit the final report and any comments to the Deciding Official, who will make the determination of whether findings from the inquiry provide sufficient evidence of possible scientific misconduct to justify conducting an investigation. The inquiry is completed when the Deciding Official makes this determination, which will be made within 60 days of the first meeting of the inquiry committee. Any extension of this period will be based on good cause and recorded in the inquiry file.

2. Notification
   The Research Integrity Officer will notify both the respondent and the whistleblower in writing of the Deciding Official's decision of whether to proceed to an investigation and will remind them of their obligation to cooperate in the event an investigation is opened. The Research Integrity Officer will also notify all appropriate institutional officials of the Deciding Official's decision.

D. Time Limit for Completing the Inquiry Report
   The inquiry committee will complete the inquiry and submit its report in writing to the Research Integrity Officer no more than 60 calendar days following its first meeting,31 unless the Research Integrity Officer approves an extension for good cause. If the Research Integrity Officer approves an extension, the reason for the extension will be entered into the records of the case and the report. The respondent will also be notified of the extension.

ORI Oversight[32]

A. Decision to Investigate
   If the Deciding Official decides that an investigation will be conducted, the Research Integrity Officer [or other designated official, if applicable] will notify ORI and will forward a copy of the final inquiry report and the institution's policies and procedures for conducting investigations to ORI.

B. Decision Not to Investigate
   If the Deciding Official decides not to proceed to an investigation and the inquiry was begun at the request of ORI or if ORI requests a copy, the Research Integrity Officer will

send a copy of the final inquiry report and the institutional decision to ORI. Otherwise, the case may be closed without notice to ORI.

C. Access to Evidence
If ORI is performing an oversight review of the institution's determination not to proceed to an investigation, the Research Integrity Officer, if so requested, will provide ORI with the report and the inquiry file including, but not limited to, sequestered evidence, analyses, and transcripts of interviews. The Research Integrity Officer will keep all records secure until ORI makes its final decision on its oversight of the institutional inquiry or investigation.

Referral to Other Agencies

Information obtained during the inquiry regarding allegations other than scientific misconduct involving PHS funds should be referred to the responsible institutional officials or government agencies. See section III.J.

Conducting the Investigation[33]

A. Purpose of the Investigation
The purpose of the investigation is to explore in detail the allegations, to examine the evidence in depth, and to determine specifically whether misconduct has been committed, by whom, and to what extent. The investigation will also determine whether there are additional instances of possible misconduct that would justify broadening the scope beyond the initial allegations. This is particularly important where the alleged misconduct involves clinical trials or potential harm to human subjects or the general public or if it affects research that forms the basis for public policy, clinical practice, or public health practice. The findings of the investigation will be set forth in an investigation report.

B. Sequestration of the Research Records
The Research Integrity Officer will immediately sequester any additional pertinent research records that were not previously sequestered during the inquiry. This sequestration should occur before or at the time the respondent is notified that an investigation has begun. The need for additional sequestration of records may occur for any number of reasons, including the institution's decision to investigate additional allegations not considered during the inquiry stage or the identification of records during the inquiry process that had not been previously secured. The procedures to be followed for sequestration during the investigation are the same procedures that apply during the inquiry. See section V.B.

C. Notification of the Respondent
The Research Integrity Officer will notify the respondent as soon as reasonably possible after the determination is made to open an investigation. The notification should include: a copy of the inquiry report; the specific allegations; the sources of PHS funding; the definition of scientific misconduct; the procedures to be followed in the investigation, including the appointment of the investigation committee and experts; the opportunity of the respondent to be interviewed, to provide information, to be assisted by counsel, to challenge the membership of the committee and experts based on bias or conflict of interest, and to comment on the draft report; the fact that ORI will perform an oversight review of the report regarding PHS issues; and an explanation of the respondent's right to request a hearing before the DHHS Departmental Appeals Board if there is an ORI finding of misconduct under the PHS definition.

D. Designation of an Official or a Committee to Conduct the Investigation
The Research Integrity Officer is responsible for conducting or designating others to conduct the investigation.
1. Use of an Investigation Committee
In complex cases, the Research Integrity Officer will normally appoint a committee of three or more persons to conduct the investigation, following the procedures set forth in section IX.E.

2. Use of an Investigation Official
In cases in which the allegations and apparent evidence are straightforward, such as an allegation of plagiarism or simple falsification or an admission of misconduct by the respondent, the Research Integrity Officer may choose to conduct the investigation directly or designate another qualified individual to do so. In such cases, the investigation official will nevertheless obtain the necessary expert and technical advice to consider properly all scientific issues.

3. Investigation Process
The investigation, whether conducted by a committee or an individual, will follow each procedural step set forth below.

E. Appointment of the Investigation Committee
If an investigation committee is to be appointed, the Research Integrity Officer will use the following procedures:
1. Committee Membership

The Research Integrity Officer, in consultation with other institutional officials as appropriate, will appoint the investigation committee and the committee chair within [suggest: 10 days] of the notification to the respondent or as soon thereafter as practicable. The investigation committee should consist of at least three individuals who do not have real or apparent conflicts of interest in the case, are unbiased, and have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses, and conduct the investigation.[34] These individuals may be scientists, administrators, subject matter experts, lawyers, or other qualified persons, and they may be from inside or outside the institution. Individuals appointed to the investigation committee may also have served on the inquiry committee.

2. Experts
   Experts may be appointed as noted in section V.E.2-4 (or carried over from the inquiry) to advise the committee on scientific or other issues.

3. Bias or Conflict of Interest
   The Research Integrity Officer will take reasonable steps to ensure that the members of the committee and the experts have no bias or personal or professional conflict of interest with the respondent, whistleblower, or the case in question. See section V.E.3.

4. Objection to Committee or Experts by Respondent
   The Research Integrity Officer will notify the respondent of the proposed committee membership within 5 days. If the respondent submits a written objection to any appointed member of the investigation committee or expert based on bias or conflict of interest, the Research Integrity Officer will immediately determine whether to replace the challenged member or expert with a qualified substitute.

5. Confidentiality
   Members of the committee and experts will agree in writing to observe the confidentiality of the proceedings and any information or documents reviewed as part of the investigation. Outside of the official proceedings of the committee, they may not discuss the proceedings with the respondent, whistleblower, witnesses, or anyone not authorized by the Research Integrity Officer to have knowledge of the investigation.

F. Charge to the Committee and the First Meeting

1. Charge to the Committee

   The Research Integrity Officer will define the subject matter of the investigation in a written charge to the committee that describes the allegations and related issues identified during the inquiry, defines scientific misconduct, and identifies the name of the respondent. The charge will state that the committee is to evaluate the evidence and testimony of the respondent, whistleblower, and key witnesses to determine whether, based on a preponderance of the evidence, scientific misconduct occurred and, if so, to what extent, who was responsible, and its seriousness.

   During the investigation, if additional information becomes available that substantially changes the subject matter of the investigation or would suggest additional respondents, the committee will notify the Research Integrity Officer, who will determine whether it is necessary to notify the respondent of the new subject matter or to provide notice to additional respondents.

2. The First Meeting

   The Research Integrity Officer, with the assistance of institutional counsel, will convene the first meeting of the investigation committee to review the charge, the inquiry report, and the 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 will be provided with a copy of these instructions and, where PHS funding is involved, the PHS regulation.

G. Developing an Investigation Plan

   At the initial meeting, the committee should begin development of its investigative plan and complete it as soon as reasonably possible. The investigation plan will include an inventory of all previously secured evidence and testimony; a determination of whether additional evidence needs to be secured; what witnesses need to be interviewed, including the whistleblower, respondent, and other witnesses with knowledge of the research or events in question; a proposed schedule of meetings, briefing of experts, and interviews; anticipated analyses of evidence (scientific, forensic, or other); and a plan for the investigative report.

H. General Approaches to Conducting the Investigation

   During the investigation, the committee will take the following steps:

1. Avoid Bias or Conflict of Interest

All necessary steps must be taken to avoid bias or conflict of interest between the committee and experts and the respondent, whistleblower, and witnesses.

2. Refer Other Issues
   The Research Integrity Officer must be advised of any necessary interim actions to protect the research funds, human or animal subjects, or other steps required by regulation or policy. See section III.E.3 and III.J.

3. Consult with the Research Integrity Officer and institutional counsel
   The Research Integrity Officer and institutional counsel should be consulted throughout the investigation on compliance with these procedures and PHS regulations, appropriate investigatory and interviewing methods and strategies, legal issues, and the standard of proof. The Research Integrity Officer and institutional counsel will be present or available throughout the investigation to advise the committee.

I. Reviewing the Evidence
   The investigation committee will obtain and review all relevant documentation and perform or cause to be performed necessary analyses of the evidence, including scientific, forensic, statistical, or other analyses as needed.

J. Conducting Interviews
   The investigation committee will conform to the following guidelines:
   1. Conducting the Interviews
      The investigation committee will conduct the interviews as described in section V.G., except that at the investigative stage interviews should be in-depth and all significant witnesses should be interviewed. Each witness should have the opportunity to respond to inconsistencies between his or her testimony and the evidence or other testimony, subject to the need to take reasonable steps to maintain the confidentiality of the testimony of the respondent and other witnesses.

   2. Preparing for Interviews
      The investigation committee will prepare carefully for each interview. All relevant documents and research data should be reviewed in advance and specific questions or issues that the committee wants to cover during the interview should be identified. The committee should appoint one individual to take the lead on each interview. If significant questions or issues arise during an interview that require committee deliberation, the committee should take a short recess to

discuss the issues. Committee deliberations should never be held in the presence of the interviewee.

3. Objectivity
   The investigation committee will conduct all interviews in a professional and objective manner, without implying guilt or innocence on the part of any individual.

4. Transcribing Interviews
   Any interview with the respondent will be transcribed or recorded. Interviews with anyone else will be summarized, tape-recorded, or transcribed. A transcript or summary of the interview will be provided to each witness for review and correction of errors. Witnesses may add comments or additional information, but changes to the transcript or summary will only be made to correct factual errors.

5. Recording Admissions
   If the respondent admits to the misconduct, he or she should be asked immediately to sign a statement attesting to the occurrence and extent of the misconduct, acknowledging that the statement was voluntary and stating that the respondent was advised of his or her right to seek the advice of counsel. The committee should consult with the institutional counsel on the specific form and procedure for obtaining this statement. The admission may not be used as a basis for closing the investigation unless the committee has adequately determined the extent and significance of the misconduct and all procedural steps for completion of the investigation have been met. The committee may ask the Research Integrity Officer or institutional counsel to consult with ORI when deciding whether an admission has adequately addressed all the relevant issues such that the investigation can be considered completed. The investigation should not be closed unless the respondent has been appropriately notified and given an opportunity to comment on the investigative report. If the case is considered complete, it should be forwarded to the Deciding Official with recommendations for appropriate institutional actions and then to ORI for review.

K. Committee Deliberations
   1. Burden and Standard of Proof
      In reaching a conclusion on whether there was scientific misconduct and who committed it, the burden of proof is on the institution to support its conclusions and findings by a preponderance of the evidence. See section III.G.

2. Definition of Scientific Misconduct
   The committee will consider whether falsification, fabrication, or plagiarism occurred in proposing, conducting, or reporting research or whether and why there was a serious deviation from accepted practices in the scientific community at the time the actions were committed.

3. Sufficient Evidence
   The committee will consider whether there is sufficient evidence of intent such that the institution can meet its burden of proving misconduct by a preponderance of the evidence. The committee will also consider whether the respondent has presented substantial evidence of honest error or honest differences in interpretations or judgments of data, such that scientific misconduct cannot be proven by a preponderance of the evidence.

The Investigation Report

A. Outline for an Investigation Report
   The following annotated outline may prove useful in preparing the Investigation Report required by the Office of Research Integrity (42 C.F.R. Part 50, Subpart A), except when special factors suggest a different approach.
   1. Background
      Include sufficient background information to ensure a full understanding of the issues that concern the PHS under its definition of scientific misconduct. This section should detail the facts leading to the institutional inquiry, including a description of the research at issue, the persons involved in the alleged misconduct, the role of the whistleblower, and any associated public health issues. All relevant dates should be included.

   2. Allegations
      List all the allegations of scientific misconduct raised by the whistleblower and any additional scientific misconduct allegations that arose during the inquiry and investigation. The source and basis for each allegation or issue should be cited except to the extent that the confidentiality of a whistleblower requesting anonymity is compromised or where the identity of the source is irrelevant or unnecessary. The allegations identified in this section will form the structure or context in which the subsequent analysis and findings are presented.

3. PHS Support
   For each allegation of scientific misconduct under the PHS definition, identify the PHS support for the research or report (e.g., publication) at issue or the application containing the falsification/fabrication or plagiarism.

4. Institutional Inquiry: Process and Recommendations
   Summarize the inquiry process, including the composition of the committee (names, degrees, departmental affiliation, and expertise), and the charge to the committee. List the persons interviewed, the evidence secured and reviewed and the measures taken to ensure its security, the policies and procedures used (or citation to the pertinent section of the institution's policies and procedures), and any other factors that may have influenced the proceedings.

5. Institutional Investigation: Process
   Summarize the investigation process, including the composition of the committee (names, degrees, departmental affiliation, and expertise), and the charge to the committee. List the persons interviewed, the evidence secured and reviewed and the measures taken to ensure its security, the policies and procedures used (or citation to the pertinent section of the institution's policies and procedures), and any other factors that may have influenced the proceedings.

6. Institutional Investigation: Analysis
   For each allegation:
   a. Background
      Describe the particular matter (e.g., experiment or component of a clinical protocol) in which the alleged misconduct occurred and why and how the issue came to be under investigation.

   b. Analysis
      The analysis should take into account all the relevant statements, claims (e.g., a claim of a significant positive result in an experiment), rebuttals, documents, and other evidence, including circumstantial evidence, related to the issue. The source of each statement, claim, or other evidence should be cited (e.g., laboratory notebook with page and date, medical chart documents and dates, relevant manuscripts, transcripts of interview, etc.).

Any use of additional expert analysis should be noted (forensic, statistical, or special analysis of the physical evidence, such as similarity of features or background in contested figures).

Summarize or quote relevant statements, including rebuttals, made by the whistleblower, respondent, and other pertinent witnesses and reference/cite the appropriate sources.

Summarize each argument that the respondent raised in his or her defense against the scientific misconduct allegation and cite the source of each argument. Any inconsistencies among the respondent's various arguments should be noted.

The analysis should be consistent with the terms of PHS definition of scientific misconduct. It should describe the relative weight given to the various witnesses and pieces of evidence, noting inconsistencies, credibility, and persuasiveness.

Describe any evidence that shows that the respondent acted with intent, that is, any evidence that the respondent knowingly engaged in the alleged falsification, fabrication, plagiarism, or other conduct that constitutes a serious deviation from commonly accepted practices.

Similarly, describe the evidence supporting the possibility that honest error or differences of scientific opinion occurred with respect to the issue.

c. Conclusions

1) Findings of Misconduct or No Misconduct

Concisely state the investigation committee's finding for each identified issue. The investigation report should make separate findings as to whether or not each issue constitutes scientific misconduct, using the PHS definition.

A finding of scientific misconduct should be supported by a preponderance of the evidence. Institutions may have their own standard of proof under their scientific misconduct policies and procedures, one that may be higher than preponderance of the

evidence. In such cases, ORI has requested institutions to reexamine the evidence and report to ORI what their conclusions would have been under a preponderance of the evidence standard.

If the investigation committee finds scientific misconduct on one or more issues, the report should identify the type of misconduct for each issue (fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the scientific community). The report should indicate the extent and seriousness of the fabrication, falsification, or plagiarism, including its effect on research findings, publications, research subjects, and the laboratory or project in which the misconduct occurred.

If the investigation committee determines that the respondent committed scientific misconduct by seriously deviating from "other commonly accepted practices," the report should thoroughly document the commonly accepted practice of the relevant scientific community at the time the misconduct occurred and indicate the extent of the respondent's deviation from that standard. Publications, standards of the institution or relevant professional societies, State and Federal regulations, expert opinion, and other sources should be described and cited as the basis for the commonly accepted practice. The serious deviation there from should be described in detail, indicating why the alleged act was a serious deviation.

2) Misconduct under the Institution's Policies

The investigation committee may determine that an action that does not constitute scientific misconduct under the PHS definition is, nevertheless, scientific misconduct under the institution's own definition (e.g., clinical protocol deviations or other violations of human subjects protection; documented animal welfare concerns; substandard data management practices; deficient mentoring of trainees). Any issue that the investigation committee determines to be scientific misconduct solely under the institution's own definition should be identified as such. These findings are not subject to ORI's jurisdiction if ORI agrees that they do not meet the PHS definition or jurisdictional basis.

7. Recommended Institutional Actions
   Based on its findings, the investigation committee should recommend administrative actions that it believes the institution should take consistent with its policies and procedures, including appropriate actions against the respondent, such as a letter of reprimand, special supervision, probation, termination, etc. The institution should also identify any published research reports or other sources of scientific information (such as data bases) that should be retracted or corrected and take steps to ensure that appropriate officials who can effect these corrections or retractions are notified.

   a. Attachments
      Copies of all significant documentary evidence that is referenced in the report should be appended to the report, if possible (relevant notebook pages or other research records, relevant committee or expert analyses of data, transcripts or summary of each interview, respondent and whistleblower responses to the draft report(s), manuscripts, publications or other documents, including grant progress reports and applications, etc.). It is also helpful to include a "List of Attachments."

      It is useful to identify allegedly false statements, misrepresentations in figures or parts of figures, areas of plagiarism, etc., on a copy of the page or section of the questioned document (e.g., a page from a research notebook). A side-by- side comparison with the actual data or material that is alleged to have been plagiarized is helpful.

B. Standard Format of the Investigation Report
   The following outline should be used in preparing the Investigation Report, except when special factors suggest a different approach. The report should incorporate all of the elements described in section X.A.

   1. Background
      - Chronology of events
      - Include public health issues

   2. Allegations

   3. PHS Support or Application(s) (by allegation)

   4. Institutional Inquiry: Process and Recommendations

- Composition of committee
- Individuals interviewed
- Evidence sequestered and reviewed

5. Institutional Investigation: Process
   - Composition of committee
   - Individuals interviewed
   - Evidence sequestered and reviewed

6. Institutional Investigation: Analysis (for each allegation)
   - Background
   - Analysis of all the relevant evidence and specific identification of evidence supporting the finding
   - Conclusion: scientific misconduct or no scientific misconduct
   - Effect of misconduct (e.g., potential harm to research subjects, reliability of data, publications that need to be corrected or retracted, etc.)

7. Recommended Institutional Actions

8. Attachments

C. Documenting the Investigative File

1. Index of Evidence
   The investigation committee should maintain an index of all the relevant evidence it secured or examined in conducting the investigation, including any evidence that may support or contradict the report's conclusions. Evidence includes, but is not limited to, research records, transcripts or recordings of interviews, committee correspondence, administrative records, grant applications and awards, manuscripts, publications, and expert analyses.

2. Purpose of Documentation
   The purpose of the documentation is to substantiate the investigation's findings.

3. Record Retention
   After completion of a case and all ensuing related actions, the Research Integrity Officer will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the Research Integrity Officer or committees. The Research Integrity Officer will

keep the file for three years after completion of the case to permit later assessment of the case. ORI or other authorized DHHS personnel will be given access to the records upon request.[35]

D. Comments on the Draft Report

1. Respondent

   The Research Integrity Officer will provide the respondent with a copy of the draft investigation report for comment and rebuttal. The respondent will be allowed 10 days to review and comment on the draft report. The respondent's comments will be attached to the final report. The findings of the final report should take into account the respondent's comments in addition to all the other evidence.

2. Whistleblower

   The Research Integrity Officer will provide the whistleblower, if he or she is identifiable, with those portions of the draft investigation report that address the whistleblower's role and opinions in the investigation. The report should be modified, as appropriate, based on the whistleblower's comments.

3. Institutional Counsel

   The draft investigation report will be transmitted to the institutional counsel for a review of its legal sufficiency. Comments should be incorporated into the report as appropriate.

4. Confidentiality

   In distributing the draft report, or portions thereof, to the respondent and whistleblower, 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 request the recipient to sign a confidentiality statement or to come to his or her office to review the report.

E. Institutional Review and Decision

   Based on a preponderance of the evidence, the Deciding Official will make the final determination whether to accept the investigation report, its findings, and the recommended institutional actions. If this determination varies from that of the investigation committee, the Deciding Official will explain in detail the basis for rendering a decision different from that of the investigation committee in the institution's letter transmitting the report to ORI. The Deciding Official's explanation should be

consistent with the PHS definition of scientific misconduct, the institution's policies and procedures, and the evidence reviewed and analyzed by the investigation committee. The Deciding Official may also return the report to the investigation committee with a request for further fact-finding or analysis. The Deciding Official's determination, together with the investigation committee's report, constitutes the final investigation report for purposes of ORI review.

When a final decision on the case has been reached, the Research Integrity Officer will notify both the respondent and the whistleblower in writing. In addition, the Deciding Official 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. The Research Integrity Officer is responsible for ensuring compliance with all notification requirements of funding or sponsoring agencies.

F. Transmittal of the Final Investigation Report to ORI
After comments have been received and the necessary changes have been made to the draft report, the investigation committee should transmit the final report with attachments, including the respondent's and whistleblower's comments, to the Deciding Official, through the Research Integrity Officer.

G. Time Limit for Completing the Investigation Report
The final investigation report will be submitted to ORI within 120 days of the first meeting of the investigation committee, unless the institution requests a written request for extension and ORI grants the extension. All attachments to the final report should be submitted with the report. The Research Integrity Officer should maintain all other evidence and materials for possible ORI review.

Institutional Administrative Actions

Stevenson University will take appropriate administrative actions against individuals when an allegation of misconduct has been substantiated.36

If the Deciding Official determines that the alleged misconduct is substantiated by the findings, he or she will decide on the appropriate actions to be taken, after consultation with the Research Integrity Officer. The actions may include:

A. withdrawal or correction of all pending or published abstracts and papers emanating from the research where scientific misconduct was found.

B. removal of the responsible person from the particular project, letter of reprimand, special monitoring of future work, probation, suspension, salary reduction, or initiation of steps leading to possible rank reduction or termination of employment;

C. restitution of funds as appropriate.

Other Considerations

A. Termination of Institutional Employment or Resignation Prior to Completing Inquiry or Investigation

The termination of the respondent's institutional employment, by resignation or otherwise, before or after an allegation of possible scientific misconduct has been reported, will not preclude or terminate the misconduct procedures.

If the respondent, without admitting to the misconduct, elects to resign his or her position prior to the initiation of an inquiry, but after an allegation has been reported, or during an inquiry or investigation, the inquiry or investigation will proceed. If the respondent refuses to participate in the process after resignation, the committee will use its best efforts to reach a conclusion concerning the allegations, noting in its report the respondent's failure to cooperate and its effect on the committee's review of all the evidence.

B. Restoration of the Respondent's Reputation[37]

If the institution finds no misconduct and ORI concurs, after consulting with the respondent, the Research Integrity Officer will undertake reasonable efforts to restore the respondent's reputation. Depending on the particular circumstances, the Research Integrity Officer should consider notifying those individuals aware of or involved in the investigation of the final outcome, publicizing the final outcome in forums in which the allegation of scientific misconduct was previously publicized, or expunging all reference to the scientific misconduct allegation from the respondent's personnel file. Any institutional actions to restore the respondent's reputation must first be approved by the Deciding Official.

C. Protection of the Whistleblower and Others[38]

Regardless of whether the institution or ORI determines that scientific misconduct occurred, the Research Integrity Officer will undertake reasonable efforts to protect whistleblowers who made allegations of scientific misconduct in good faith and others who cooperate in good faith with inquiries and investigations of such allegations. Upon

completion of an investigation, the Deciding Official will determine, after consulting with the whistleblower, what steps, if any, are needed to restore the position or reputation of the whistleblower. The Research Integrity Officer is responsible for implementing any steps the Deciding Official approves. The Research Integrity Officer will also take appropriate steps during the inquiry and investigation to prevent any retaliation against the whistleblower.

D. Allegations Not Made in Good Faith
If relevant, the Deciding Official will determine whether the whistleblower's allegations of scientific misconduct were made in good faith. If an allegation was not made in good faith, the Deciding Official will determine whether any administrative action should be taken against the whistleblower.

E. Interim Administrative Actions
Institutional officials will take interim administrative actions, as appropriate, to protect Federal funds and ensure that the purposes of the Federal financial assistance are carried out.[39]

ORI Review of the Investigation Report and Follow-up[40]

A. Purpose of ORI Review
ORI reviews the final investigation report, the supporting materials, and the Deciding Official's determinations to decide whether the investigation has been performed in a timely manner and with sufficient objectivity, thoroughness, and competence. Based on its review, ORI may:
    1. request additional information from the institution;
    2. accept all the findings and conclusions of the report;
    3. accept all or part of the factual findings of the report and make its own conclusions;
    4. request additional investigation by the institution;
    5. reject the report and conduct its own investigation;
    6. impose administrative actions on the respondent beyond those recommended by the institution;
    7. refer the case to the Division of Policy and Education, ORI, for a review of the institution's regulatory compliance;41 or

8. take any other action deemed to be in the public interest and within ORI's authority.

ORI will attempt to complete its review of the institution's report within 180 days of its receipt, except where additional follow up activities are required, such as an ORI request for additional information or analysis or where further investigation is necessary.

B. Cooperation with ORI Review[42]

ORI is authorized by statute and PHS regulations to review institutional reports on allegations of scientific misconduct. In reviewing an institution's report, ORI may request additional information or other assistance from the Research Integrity Officer or other institutional officials. If the institutional official receiving the ORI request is unsure how to respond, he or she should consult with the Research Integrity Officer or institutional counsel. Institutional counsel may consult with ORI counsel prior to advising the institutional official on how to respond.

C. Request for Additional Documents and Information

The Research Integrity Officer will cooperate with any ORI request for additional documents and information by responding to all requests in a timely and responsive fashion. The Research Integrity Officer may consult with institutional counsel for advice as needed.

D. Notification of ORI Determination

1. ORI Concurrence

If ORI concurs with the institution's findings, ORI will notify the respondent and appropriate institutional officials in writing and will send the respondent and appropriate institutional official a summary or copy of the concurrence and notice of any additional PHS actions. If there is an ORI finding of scientific misconduct, the respondent will be notified of his or her opportunity to appeal to the DHHS Departmental Appeals Board (DAB). See 59 Fed. Reg. 29809 (1994).

2. ORI Nonconcurrence

If ORI does not concur with the institution's findings, ORI will notify the appropriate institutional official of the basis for that decision. If ORI does not concur with a finding of no misconduct, the institution may be requested to conduct a further investigation, either with the same or a different investigation committee, or ORI may conduct its own investigation. In the latter instance, ORI will notify the appropriate individuals of its investigation.

E. Cooperation in Appealed Cases[43]

For cases in which ORI concurs with the institution's findings of scientific misconduct under the PHS definition or makes its own finding of scientific misconduct, ORI will request institutional employees to cooperate in presenting ORI findings of misconduct before the DAB if the respondent appeals the findings.

Cooperation includes providing evidence, testimony, or any other information needed to assist in the preparation and presentation of ORI's case before the DAB. Institutional employees may consult with the Research Integrity Officer or institutional counsel in responding to ORI's request for cooperation.

Record Retention[44]

After completion of a case and all ensuing related actions, the Research Integrity Officer will prepare a complete file, including the records of any inquiry or investigation and copies of all documents and other materials furnished to the Research Integrity Officer of Committees. The Research Integrity Officer will keep the file for at least three years after completion of the case to permit later assessment of the case. ORI or other authorized DHHS personnel will be given access to the records upon request.

NOTES

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1. *Some of the definitions in this section are based on the Public Health Service regulations. 42 C.F.R. ' 50.102.*
2. *42 C.F.R. ' 50.103(d)(13); See also, 42 U.S.C. ' 289b(e).*
3. *Id.*
4. *42 C.F.R. " 50.103(d)(3) and (13) and '50.104(a)(2).*
5. *42 C.F.R. " 50.103(d)(2) and (3).*
6. *42 C.F.R. ' 50.104(a)(6).*
7. *42 C.F.R. ' 50.103(d)(9).*
8. *42 C.F.R. ' 50.103(d)(5) and '50.104(b)(1)-(5).*
9. *42 C.F.R. 50.103(d)(11).*
10. *42 C.F.R. 50.103(c)(3) and (4) and 50.104(a)(6).*
11. *Section XI of the Hearing Procedures for Scientific Misconduct, 59 Fed. Reg. 29809,*
12. *29811, June 9, 1994; 45 C.F.R. " 76.313(c)(1) and (2).*
13. *42 C.F.R. ' 50.104(a)(3).*
14. *42 C.F.R. ' 50.104(b)(5).*
15. *42 C.F.R. ' 50.104(a)(1).*
16. *42 C.F.R. ' 50.104(a)(1).*
17. *42 C.F.R. ' 50.103(d)(15).*
18. *42 C.F.R. ' 50.104(a)(3).*
19. *42 C.F.R. ' 50.104(a)(5).*
20. *42 C.F.R. ' 50.104(a)(3).*
21. *42 C.F.R. ' 50.104(b)(1).*
22. *42 C.F.R. ' 50.104(b)(2).*
23. *42 C.F.R. ' 50.104(b)(3).*
24. *42 C.F.R. ' 50.104(b)(4).*
25. *42 C.F.R. ' 50.104(b)(5).*
26. *42 C.F.R. ' 50.103(d).*
27. *42 C.F.R. ' 50.103(d)(1).*
28. *42 C.F.R. ' 50.103(d)(1).*
29. *42 C.F.R. " 50.103(d)(1) and (3).*
30. *42 C.F.R. ' 50.103(d)(1).*
31. *42 C.F.R. " 50.103(d)(4) and (7).*
32. *42 C.F.R. ' 50.103(d)(1).*
33. *42 C.F.R. ' 50.103(d)(6) and 42 C.F.R. '*

34. 50.103(d)(10).
35. 42 C.F.R. ' 50.103(d) and ' 50.104.
36. 42 C.F.R. ' 50.103(d)(8)
37. 42 C.F.R. ' 50.103(d)(10).
38. 42 C.F.R. 50.103(d)(14).
39. 42 C.F.R. ' 50.103(d)(13).
40. 42 C.F.R. ' 50.103(d)(13).
41. 42 C.F.R. ' 50.103(d)(11).
42. 42 C.F.R. ' 50.103(d)(11).
43. 42 C.F.R. ' 50.105.
44. 42 C.F.R. ' 50.104(a)(6); 42 C.F.R. '
45. 50.103(c)(4).
46. 42 C.F.R. ' 50.103(d)(4).
47. 42 C.F.R. ' 50.103(d)(4)