Faculty Senate Resolution #12-39

Approved by the Faculty Senate: March 27, 2012

Approved by the Chancellor: May 2, 2012 (with changes noted in highlight)

Revisions to the ECU Faculty Manual, Part VII. Research Information

Link to current Part VII. located in the ECU Faculty Manual.

Revise and keep in the Faculty Manual.

Part VII. Faculty Research and Scholarship

CONTENTS

- I. Faculty Research, Creative Activity, Scholarship, Innovation, Engagement, and Outreach
- II. Scholarship/Research/Creative Activity Guidelines
 - A. Funded Research
 - B. Principles and Policy for the Protection of Human(s) in Research
 - a. Statement of Ethical Principles
 - b. Institutional Policy
 - c. Implementation of Policy
 - C. Animal Welfare Regulations
 - D. Research Data and Records
 - E. Patents
 - F. Copyrights (created work)
- III. Ethics in Research and Creative Activity
- I. Faculty Research, Creative Activity, Scholarship, Innovation, Engagement, and Outreach Faculty scholarship includes the scholarship of research, the scholarship of creative activity/innovation, and the scholarship of engagement and/or outreach. Scholarship is a fundamental faculty activity, and faculty have freedom to pursue scholarship on the subjects of their choosing. The quality of the scholarly works that faculty produce should be based on the standards of the profession as determined by the community of scholars with the expertise and training to establish these standards. Appendix C of the ECU Faculty Manual establishes general criteria for the evaluation of scholarship in the appointment and promotion of faculty members and requires that the relative importance of each type of scholarly activity be clearly defined in the unit code. Faculty have the obligation to adhere to the research and scholarship guidelines established by East Carolina University, the federal government, and the community of scholars. This document provides guidelines for research and scholarship established by the ECU faculty and references to research and scholarship policies, rules, and regulations (PRRs) as well as research- and scholarship-related standard operating procedures established by East Carolina University.

Research and scholarship also form a basic part and are integrally linked to the faculty members' teaching responsibility. Original results of research and scholarship inform faculty members' interactions with students at all levels. Deeper understanding of research and scholarship is conveyed when faculty develop students so that they may participate in research and scholarly activities. Effective mentoring of students is critical to their transition to independent research and scholarship. While this document focuses on faculty research and scholarship, it also provides references to research- and scholarship-related PRRs relevant to collaborative scholarly work involving faculty and students.

II. Scholarship/Research/Creative Activity Guidelines

This section and the related policies and regulations referenced within the section, contain guidelines for ECU researchers and scholars. Many of these guidelines are dictated by federal law and institutional policies and procedures. Guidelines within this section include those for externally funded research and scholarship, protection of humans in research, animal welfare in research, retention of research data and records, patents that arise from scholarly activity, and copyright of scholarly material produced by faculty. Faculty members are expected to be familiar with and to follow the guidelines that apply to their research and scholarly activities.

A. Funded Research

As a constituent institution of The University of North Carolina, East Carolina University receives its basic financial support from appropriations by the North Carolina General Assembly and from tuition and fees paid by students. However, to achieve and maintain a higher level of excellence than is possible with those funds and in accordance with the mission and strategic plan of ECU, grants and contracts are sought from governmental and other sources as well as gifts from alumni, friends, corporate entities, and foundations.

1. Definitions

Gift - A gift is an item of value, ownership of which is voluntarily transferred from one party to East Carolina University or one of ECU's foundations without direct compensation to the first party. Gifts may be in the form of cash or in kind (e.g., art objects, equipment, securities, real estate, services, insurance, etc.). Gifts may be solicited (given in response to a request from ECU) or unsolicited (given at the donor's own initiative). Gifts are generally classified as unrestricted, i.e., use or disposition of the gift is at the discretion of the university. Visit http://www.ecu.edu/cs-acad/grants/Policies.cfm, "Gifts vs. Grants" for more information.

Contract – The principal purpose of a contract is the acquisition of property or services for the direct benefit or use by the Government or other sponsor. The sponsor may select from several candidates to carry out the project and typically exerts fairly strict management control over the contract recipient. Contracts are typically awarded by the federal government in response to requests for proposals (RFP's), by state and local government agencies, and by for-profit commercial entities (single owner companies, partnerships, and corporations).

Grant – The purpose of a grant is to transfer money, property, services or anything of value from the government or other sponsor to the recipient in order to accomplish a public purpose. A grant is typically awarded for projects where most or all of the factors outlined above have not yet been determined. Grants are frequently awarded for experimental projects or for projects where the idea and purpose of the award have been suggested by the grantee. The grantee works independently and has considerable latitude in accomplishing the aims and goals of the project. Grants are typically awarded by the federal government and by private nonprofit foundations and organizations. The outcomes of the project are typically not of direct benefit to the sponsor of a grant.

Cooperative Agreement –A cooperative agreement is like a grant; however, the government or sponsor expects to be more involved in project planning and implementation. The funding agency retains an interest in procedures, timetables, etc. and works cooperatively with the awardee in order to share responsibility for achievement, changes in methods, delays, etc. A cooperative agreement is most likely to be used by certain agencies of the federal government, again to accomplish a public purpose.

2. Fundraising and Gifts

While all members of the university community are encouraged to participate in the process of identifying and qualifying prospective funding sources, the vice chancellor for institutional advancement is responsible for the coordination of all fund raising activities at the university which are direct gift solicitations. No solicitation or acceptance of gifts shall be made by any faculty member in the name of or for the benefit of the university without prior clearance through the Office of Institutional Advancement. Exceptions to this restriction may be documented in the PRRs for Institutional Advancement. Procedures for fundraising and the solicitation and acceptance of gifts are included in the Institutional Advancement PRRs.

ECU REG04.05.01. Gifts Affecting the Curriculum ECU REG04.05.02. Coordination of Private Gift Fund-Raising Activities at East Carolina University

3. Contracts, Grants, and Cooperative Agreements

All proposals to governmental, private nonprofit, or corporate agencies or organizations for a contract, grant, or cooperative agreement to support research (including clinical research), instruction, public service, or other creative activities to be conducted by any faculty or staff member or other person associated with the university shall be coordinated, reviewed and approved in advance of submission to the sponsor with the Office of Sponsored Programs.

B. Principles and Policy for the Protection of Humans in Research

East Carolina University acknowledges and accepts its responsibilities for protecting the rights and welfare of individuals who act as participants in research conducted by its faculty, staff and students. The protection of humans in research activities was dealt within a president's (chancellor's) policy memorandum dated May 22, 1970. This earlier memorandum is hereby amplified and superseded.

1. Statement of Ethical Principles

East Carolina University has adopted as a guiding statement of ethical principles the three principles as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research dated April 18, 1979, and entitled The Belmont Report:

Ethical Principles and Guidelines for the Protection of Human Subjects of Research include respect for persons, as implemented through the informed consent process and documents, beneficence which is applied through the analysis of known risks versus potential benefits, and justice which ensure that the burden of research is not placed on any one population and the benefits of research are open to all who might gain from their participation.

In addition, East Carolina University acknowledges and accepts the requirements set forth in the Department of Health and Human Services Title 45 Code of Federal Regulations Part 46 (45 CFR 46) for all research involving humans regardless of funding source. ECU also applies the Food and Drug Administration regulations found at Title 21 CFR Parts 11, 50, 56, 312, 600, and 812 to all human research classified as a "clinical investigation" or that involves an article that falls within FDA's purview. ECU also applies, as applicable, regulations from the Department of Defense, Department of Education, and other DHHS agencies. With international human research, ECU applies regulations set forth by the International Council on Harmonization.

2. Institutional Policy

It is the policy of East Carolina University that all research activities involving humans, through direct intervention or interaction or the use of private, identifiable information about humans, and that are conducted by its faculty, staff or students must be submitted, reviewed, and approved by an appropriately established peer-review committee known as an Institutional Review Board. At ECU, there are three such committees, the Biomedical University Medical Center Institutional

Review Board (UMCIRB), the Social and Behavioral Institutional Review Board (BSS IRB) and the Summer Social and Behavioral Institutional Review Board (SBSS IRB). These committees consist of scientists, non-scientists and community members. The committee must meet federally mandated membership requirements. Committee members serve four year terms, as appointed by the Vice Chancellor of Research.

The Office for Human Research Integrity (OHRI) is responsible for providing support to ECU's IRBs, the Vice Chancellor for Research, and faculty, staff and students who wish to engage in human research activities. OHRI also is responsible for providing education, quality improvement reviews, and orientation activities to IRB members, investigators and research personnel. It is the responsibility of this Office to make recommendations for IRB membership to the Vice Chancellor of Research to ensure compliance with federal regulatory requirements.

It is the responsibility of the OHRI staff, with consultation from IRB Chairs and Vice Chairs, to determine whether a research activity meets the definition of human research. This determination cannot be made by investigators, research personnel, or other bodies within ECU.

The type of review mechanism that a proposed research activity may receive is based upon criteria set forth in the federal regulations.

Researchers wishing to conduct human research activities must first complete training in human research protections. This training is offered through the Office of Human Research Integrity and can be accessed through its website at www.ecu.edu/irb.

It is the responsibility of Faculty acting as mentors to students conducting human research activities to ensure that the students complete the necessary training before submitting their applications through e-PIRATE, the electronic submission and review system found on the OHRI website.

East Carolina University requires all principal investigators and their research teams to comply fully with the appropriate federal regulations, institutional policies, and the UMCIRB Standard Operating Procedures.

3. Implementation of Policy

In all activities involving human research participants, the chairperson of the pertinent department or head of the academic unit is responsible for ensuring that the proposed research activities are scientifically sound, that the methods and procedures will adequately address the research question, and that the proposed research fits with the mission of the department or academic unit as well as the university.

The principal investigator is responsible for conducting the research according to the ethical principles of the discipline, the ethical principles of the Belmont Report, university policies and procedures, and the methods and procedures approved by the Institutional Review Board.

The IRB has the federally mandated authority to approve, modify or disapprove proposed research. It also has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants.. The IRB is obligated to report suspension and terminations through a report to the investigator, institutional officials, and sponsoring agency, if any. Principal investigators of research studies involving humans must submit a complete protocol and address all applicable questions in e-PIRATE, upload appropriate informed consent and assent documents, and any other study related materials. Access to the electronic system,

e-PIRATE, requires completion of human research protections training, registering with OHRI through e-PIRATE, and completing an Investigator Profile. A copy of all research study materials including signed informed consent and study related correspondence must be maintained by the principal investigator for at least 3 years, or longer if required by the research sponsoring agency.

If the research involves Protected Health Information or storage of data outside of ECU's maintained servers, additional requirements must be met. More information on those requirements can be found at www.ecu.edu/hippa or on the IRB website. Research documents that involve protected health information must be maintained for a minimum of 6 years beyond the end of the project.

Investigators are responsible for reporting the progress of UMCIRB-approved research to the Office for Human Research Integrity, through the use of a renewal or continuation review accessed through e-PIRATE. Federal regulations require that IRB approval be issued no less often than once per year as set forth in 45 CFR 46.109. In addition, research investigators are responsible for reporting promptly to their department chair and to the OHRI, any unanticipated problems which involve risks to the research participants or others.

C. Animal Welfare Regulations

The ECU Institutional Animal Care and Use Committee (IACUC), in conjunction with the University Attending Veterinarian (AV) and the Institutional Official (IO- vice chancellor for research and graduate studies), are charged with oversight of vertebrate animal care and use activities. Federal regulations require that anyone (faculty, staff, students) using vertebrate animals in research, teaching, and testing must obtain approval from the ECU IACUC prior to initiation of the activity. Animal Use Protocol (AUP) forms and additional information such as training requirements, occupational health and safety requirements, mechanisms for reporting animal welfare concerns, IACUC operations, rules and guidelines, and links to other relevant websites (e.g., the Department of Comparative Medicine home page: http://www.ecu.edu/comparativemedicine/, and the Prospective Health home page: http://www.ecu.edu/cs-dhs/prospectivehealth/index.cfm are located on the IACUC website (https://www.ecu.edu/iacuc/). The ECU IACUC regulations must comply with all relevant Federal regulations (for more information see: USDA Animal Welfare Act and Regulations (http://www.aphis.usda.gov/animal_welfare/), PHS Policy on Humane Care and Use of Laboratory Animals and Guide to the Care and Use of Laboratory Animals (http://grants.nih.gov/grants/olaw/olaw.htm).

D. Research Data and Records

1. Purpose

The preparation and retention, of accurate and appropriate records are essential components of a credible research endeavor. East Carolina University, its faculty, staff, and students have a common interest and a shared responsibility to assure that research data and records are recorded appropriately, archived for a reasonable length of time, and available for review by scholars and others under appropriate circumstances. Original research records are also essential to protect intellectual property rights, to answer ongoing questions regarding the management of a research program, and to address questions that may arise regarding the propriety of research conduct and methods. This policy defines the nature of research data and its associated records. It also describes the importance of good data and record keeping for obtaining and defending intellectual property rights, and the procedures to be used for the custody, retention, access, and transfer of research data and records.

This policy shall apply to all faculty, staff, and students of East Carolina University who are involved in the design, conduct, and/or reporting of research at or under the auspices of East

Carolina University, regardless of source of funding.

2. Definition of Research Data and Records

Research data and records refers to recorded information, regardless of its form or the media on which it may be recorded, which is necessary for the reconstruction and evaluation of the reported results of a research project. Research data and records include more than just primary data (e.g., raw numbers generated by a measuring instrument; audiotapes or transcripts of survey interviews). They also include documentation or citation of a) the experimental methods for data collection, and b) the methods used for data processing and interpretation. In practice, they include, but are not limited to, the material contained in laboratory notebooks or other media such as computer disks and machine printouts. The term does not include the intellectual property generated by a research project; administrative information, such as financial data; or the tangible products of research, e.g., tissue banks, specialized tools or chemicals produced by the project. (Ownership and disposition of intellectual property or the tangible products of research are covered by other ECU policies.)

3. Intellectual Property Issues Involving Research Data and Records Retention of maximum intellectual property rights places additional importance on the preparation and retention of research data and records. Documented research records are important in determining priority of research data, such as identifying who first conceived an invention or in defending against patent infringement. In order to protect the rights of investigators and the university to the intellectual property generated by their research programs, university technology transfer managers recommend specific record keeping and retention practices such as the use of bound laboratory notebooks. Maintaining good data records is recommended for all university laboratories, but is essential for any patentable or licensable research activity. Responsible faculty should be aware of and follow, as closely as possible, the record-keeping recommendations described in Addendum B. Section II of the OPERATIONAL PROCEDURES FOR IMPLEMENTATION OF FACULTY MANUAL PART VII, SECTION II http://www.research2.ecu.edu/ott/operating.html. The data management approaches above will also help defend an investigator and his/her work if there is an allegation of misconduct regarding this research.

4. Custody of Research Data and Records

Custody of original research data and records is the responsibility of the senior investigator of a project, usually a faculty member. This senior investigator (the responsible investigator) must ensure the integrity, preservation and security of the original research data and records. Expenses of data and record preservation and security are allowable costs to sponsored programs. As an aid to scholars and other appropriate individuals who may wish to review the research data and records, all research records must be appropriately organized and labeled to allow the identification of specific information within the records by someone who was not involved with the original project.

In situations where the vice chancellor for research and graduate studies (the designated ECU Integrity Officer) has received an allegation of research misconduct pursuant to ECU policy (Faculty Manual Part VII Section VI) or when patent litigation is imminent, the university may take immediate and preemptory custody of the original research data and records relating to the allegation or the patent. In this circumstance the university shall provide needed copies of data and records to the investigator that will allow active research projects to continue.

In multi-institutional studies, contractual agreements often stipulate that the home institution of the primary study director shall have custody of original primary data from all participating institutions. In situations where ECU is not the site of the home institution and will need to transfer the original data to the institution of the study director, ECU shall retain a true copy of all data and records generated for the multi-institutional study.

Senior members of research teams have obligations and are held responsible for discussing the responsibilities of data management and retention with other members of the research team. The senior member of the research team must directly oversee the data and record management of the technicians, post-doctoral fellows, students, and others working under his/her direct supervision.

5. Access to Research Data and Records

The university ultimately owns data and support records generated by its faculty, staff and students. Therefore the university has the right of access to (and to make copies of) the data and records for all research performed at the university or under university auspices provided such access to the records shall be for reasonable cause, at reasonable times and after reasonable notice (except in cases of misconduct allegations, see below). For example, the University Medical Center Institutional Review Board, the office for Human Research Integrity staff, and the Brody School of Medicine Compliance office, and office for Research Compliance Administration, acting for the university, may review records and study data of projects that use human participants to assure compliance with regulatory human research protections. In cases involving an allegation of research misconduct, the university through the vice chancellor for research and graduate studies may request immediate, preemptory access and custody of original research records. When such records contain confidential information about human participants in research, the vice chancellor shall institute appropriate procedures to assure that participant confidentiality is maintained while the research records are in his custody.

Extramural sponsors providing support for East Carolina University and appropriate governmental officials also have the right to review the data and records resulting from that extramural support. In addition, investigators, co-investigators, students, visiting researchers, and students who are or were an integral part of a research project team have the right to review all records and data which are part of that project or support publications for which they are named authors. Similarly, investigators, co-investigators, students, visiting researchers, and students have a right to a copy of data that they personally generated or substantially analyzed unless prohibited by law, regulation, or contractual agreements. The responsible investigator in addition has the right to distribute to other scholars or individuals copies of any part the research records in his custody per the general practices of his/her field of study unless prohibited by law, regulation, or contractual agreements.

6. Retention of Research Data and Records

Research data and records, including the primary experimental results, should be retained for a sufficient period to allow evaluation and repetition by others of published results emanating from those data. In general, five years from the first publication date of the research results is specified as the minimum period of retention for research published in peer-reviewed journals. For sponsored research that is not published, the minimum retention period is five years from the date of the issuance of the final report to the research sponsor, unless the sponsor specifies a longer retention period. However, if an investigation, legal action or an official inquiry concerning a research project is underway, all data and records related to the project must be retained and made accessible until all issues are resolved. In addition, the records should be kept for as long as may be required to protect any patents or other intellectual property resulting from this work. If a research project is not funded with external or designated internal funds (e.g., an internal university grant), the above retention policy shall apply to these research data and records only

when the project results in a publication, its data is used to support a grant or contract application, or it involves the use of animals or human participants. If research involves the generation, use, or disclosure of protected health information (PHI), the minimum retention of those records including consent and authorization agreements must be maintained for a minimum of six years beyond the end of the project. If a participant withdraws authorization of use of PHI, the researcher must consider that request to constitute the end of the project and Day 1 of the six year retention period for that sample.

7. Transfer of Research Data and Records that Support University Patents or Were Funded by Federal Grants and Contracts

Pursuant to federal regulations (OMB Circular A-110, section 53) and the need of the university to protect its patent rights, original research data and records that support university patents or were funded by federal grants and contracts must remain in the custody of the university for the required retention period as discussed above. In the event the responsible investigator transfers to another institution or leaves the university for any reason the responsible investigator shall transfer custody of these original research data and records to the university. Exceptions to this policy are discussed at the end of this section. The responsible investigator, however, may make a copy of the data and research records at university expense for his/her personal use at a new institution unless prohibited by law, regulations or contractual agreements. Before his/her departure, the responsible investigator shall transfer custody of the original research data and records to his/her department chair or supervisor as required by this policy. These records shall be retained in the University Archives of Joyner Library pursuant to the retention paragraph above. These data and records shall be organized in a format to permit reasonable identification of specific experiments and data by individuals not involved with the original research.

These research data and records shall be used by the university only for patent litigation, misconduct inquiries and investigations, or for other purposes required by federal regulations for US government funded research.

Exceptions:

- 1) Currently Active Federal Grants and Contracts: If the responsible federal agency allows the transfer of an active grant or contract to the new institution of the principal investigator, and the new institution accepts the administrative responsibility for the federal award, the original research data and records may be transferred to the new institution upon the request of that institution. The university, however, shall retain a true copy, made at university expense, of all research records produced while the research project was active and under ECU jurisdiction.
- 2) Faculty Request for Transfer of Original Records: Per OMB Circular A-110 section 53c, a faculty member may request authorization from the responsible federal agency to substitute true copies of the research data and records in the University Archives in place of the originals. If so authorized, the investigator may then transfer his/her original data and records to the new institution.
- 3) Multi-Institutional Federal Grants and Contracts: If such federal awards designate a specific institution as the depository of original data and records for a multi-institutional project, the university shall comply with this requirement. However, the university shall retain a true copy of the original records produced at university expense.

8. Transfer of other Research Data and Records

In the event the responsible investigator transfers to another institution or leaves the university for any reason, the responsible investigator shall provide a true copy at university expense of his/her research data and records that have been retained less than five years in the

investigator's possession per the retention paragraph above. Before his/her departure, the responsible investigator shall provide these true copies of the research data and records to his/her department chair or supervisor. These data and records shall be organized in a format to permit reasonable identification of specific experiments by individuals not involved with the original research. These research data and records shall be used by the university only for misconduct inquiries and investigations,

9. Resolution of Disputes Involving Research Data and Records

The vice chancellor for research and graduate studies or his designee shall arbitrate all disputes involving research data ownership, retention, and access. Whenever possible, the Vice Chancellor or designee shall first attempt to mediate a resolution to the dispute acceptable to all parties. When the dispute involves faculty from the School of Medicine or the College of Arts and Sciences, the Vice Chancellor or designee shall consult with the designated Associate Deans for Research in those units.

E. Patents

East Carolina University is dedicated to the pursuit of instruction, research and scholarship, as well as engagement and innovation development activities, in an environment that is open to collaboration and publication. Inventions, discoveries and other intellectual assets sometimes arise as a result of these activities. These assets may qualify for intellectual property protection in the form of patents, copyrights, trademarks, and trade secrets. The Board of Governors of the University of North Carolina has determined that patenting and commercialization of these intellectual assets are consistent with the mission of the university.

The patent policy of the University of North Carolina is contained in Part 500.2 of the University of North Carolina Policy Manual. The patent policy of East Carolina University is contained in PRR (add link once PRR is approved). These policies address ownership of university inventions, distribution of income derived from licensing, assignment, or commercialization activities related to university inventions, and management of disputes. The patent policies also recognize limited circumstances in which publication of scholarly works may be delayed for short periods of time to allow for filing of patent applications. Premature publication or public use of an invention can constitute a statutory bar to the granting of a patent. In most cases, inventors may publish, present, and discuss their inventions freely once a patent application has been filed.

F. Copyrights (created work)

1. Introduction

East Carolina University (hereinafter referred to as "the university") has among its primary purposes teaching, research, and the expansion and dissemination of knowledge. Products of these endeavors include development and use of copyrightable materials. The creation of copyrightable materials in the form of literary, dramatic, and other intellectual works by the university community is encouraged as a measure of productivity and commitment to the dissemination of knowledge and creative activity for public benefit. It is the policy of this university that its faculty, staff, and students carry out their scholarly work in an open and free atmosphere that encourages publication without constraint, consistent with applicable laws and university policy. The Copyright Policy contained herein is consistent with the Copyright Use and Ownership Policy of the University of North Carolina, enacted by the Board of Governors on November 10, 2000.

2. Scope and Coverage

This policy applies to the faculty, staff, and students of the university. Compliance with the terms of this policy is a condition of employment for university faculty and staff, and of enrollment for

university students. This policy is supplemental to the Copyright Use and Ownership Policy of the University of North Carolina, and is subject to any applicable laws and regulations and to specific provisions in grants or contracts that govern rights in copyrighted works created in connection with sponsored research.

3. Definitions

Assign: The transfer of one or more of the ownership rights in a work from the copyright owner to another person or organization.

Author or Creator: Someone who originates or contributes copyrightable expression such as poetry, prose, computer programming, artwork, musical composition/work, recorded music, animations, video footage, web pages, architectural drawing, and photographs.

Copyright License: Written permission to use copyrighted material that is usually limited to a period of time and/or for a particular use.

Directed Works: Works that are specifically funded or created at the direction of the university, and which may or may not include exceptional use of university resources.

Derivative Works: Works based upon and substantially similar to a pre-existing work, that would infringe the pre-existing work without a license from the author of the pre-existing work.

EPA Non-Faculty Employee: Employees designated as exempt from the North Carolina State Personnel Act who hold an approved administrative or non-teaching position.

Exceptional Use of University Resources: Resources/Support provided by the university for the creation of a work that is of a degree or nature not routinely made available to university employees. An example of exceptional use would be the use of support staff for graphics design, or computer programming, that is not normally provided to university employees. Ordinary use of computers, FAX machines, laboratory space, libraries, office space or equipment, secretarial services at routine levels, telephones, and other informational resources, such as the virtual reality system or other special computing equipment, shall not be considered exceptional use of university resources. Whether an individual work has been created through exceptional university resources shall be determined initially by the chair or director of the department in which the creator has principally been involved or from which he or she has received resources to fund the work, taking into account the nature and amount of resources customarily made available to faculty or staff in that department. At the time that exceptional resources are approved, the unit administrator of that particular area of research shall inform that faculty member.

Faculty: Employees designated as exempt from the North Carolina State Personnel Act (EPA Employee) who hold one of the professorial ranks of instructor, assistant professor, associate professor, or professor, or whose title is lecturer, visiting professor, clinical professor, adjunct professor, research associate professor, post doctoral fellow or the like.

Fair Use: A use of copyrighted material for purposes of criticism, comment, news reporting, teaching, scholarship, or research, which is not an infringement of a copyright. Fair Use is further discussed in Section IV of this document.

Publication: The public distribution of copies of a work or the original work by sale or other transfer of ownership, including rental, lease or loan.

Royalty: A payment made to the owner of a copyrightable work for use of the work.

SPA Staff (to include CSS employees): Employees designated by the North Carolina State Personnel Act who generally perform a support role for the university.

Shop Right: A non-exclusive, non-transferable, royalty-free right to use a copyrightable work for educational or research purposes.

Sponsored Work: Funds supplied under a contract, grant, or other arrangement between the university and a third party, including a sponsored research agreement.

Student: Any individual currently enrolled in the university or its extension programs in undergraduate, graduate or other academic classes. Teaching, research and graduate assistants are included for the purposes of this Copyright Policy.

Student Works: Papers, computer programs, theses, dissertations, artistic and musical works, and other creative works made by students.

Traditional or Non-Directed Works: Pedagogical, scholarly, literary, or aesthetic (artistic) works originated by faculty or EPA non-faculty employees who maintain creative control over the work.

Works for Hire: A work prepared by an employee within the scope of his or her employment or a work specifically commissioned where the contractual agreement clearly specifies the work shall be considered a work made for hire.

4. Copyright Ownership

Ownership of copyright in copyrighted works shall depend on the category of the work in question and its creator.

Works by Faculty and EPA Non-Faculty Employees

The ownership of traditional or non-directed works shall remain with the creator except in the following circumstances:

- a. Directed Works
 - Ownership of directed works shall remain with the creator and the university shall retain a shop right for use of the work. Upon written agreement between the university and the creator, the university may release or transfer its rights in the work to the creator provided, however, the university maintains a shop right to use of the work. Expense reimbursement and income sharing with the university shall be considered.
- b. Works Involving Exceptional Use of Institutional Resources Ownership shall remain with the university except, upon written agreement between the university and the creator, the university may release or transfer its rights in the work to the creator provided, however, the university maintains a shop right for use of the work. Expense reimbursement and income sharing with the university shall be considered.
- c. Sponsored Works Requiring the University's Ownership Ownership shall be decided in accordance with the terms of the sponsored programs agreement with the university:
 - i) Institutional Ownership: In the case of institutional ownership, provided there is no conflict with a sponsored agreement, the university may:
 - a) Release or transfer its right to the creator under an agreement with the creator;
 - b) Negotiate with the creator for joint ownership of the work;
 - c) Require a shop right for the university's use of the work;

- d) Require expense reimbursement upon commercialization of the work; and/or
- e) Require income sharing upon commercialization of the work.
- ii) Ownership Not Addressed in Agreement: Provided the sponsored agreement does not expressly require copyright ownership by the university or a third party, ownership shall remain with the creator subject to disclosure to the university provided, however, the university shall, if practical, be assigned a shop right for use of the work.

d. Works by SPA Staff

Works for hire made by SPA staff, working within the scope of their employment, shall be owned by the university except the university may enter into a written agreement in advance to transfer copyright ownership to the SPA staff employee.

e. Works by Independent Contractors

Works developed by independent contractors shall be owned in accordance with the contract under which the work was created. The university unit entering into arrangements for work to be produced by an independent contractor shall insure that the written contract specifies institutional ownership. Any exceptions shall be approved by the appropriate Vice Chancellor or designee.

f. Works by Students

Students may produce works while carrying out activities related to their enrollment at the institution or while employed by the institution. Examples of student works are papers, computer programs, theses, dissertations, artistic works, and musical works. Copyright ownership of student works shall remain with the student except in the following circumstances:

- Sponsored or Externally Contracted Works
 Ownership shall be in accordance with Section 4.iii of this Copyright Policy,
 Sponsored Works Requiring the University's Ownership, hereinabove.
- ii) Works for Hire

Student works created in the course of employment with the university shall be considered Works for Hire and shall be owned by the university.

iii) Derivative Works

The sale or commercial use of derivative works without the express written permission of the author may violate the copyright rights of the author. Commercial exploitation of these materials (which may include faculty lectures, notes from faculty lectures, syllabi, and other course materials) without express written permission of the instructor may result in disciplinary action in accordance with university policies.

5. Joint Ownership

Copyright holders, including faculty, EPA non-faculty employees, SPA staff employees and students may enter into written joint ownership agreements with one another at their discretion, with the approval of the Chancellor or his designee.

6. Administration

University Committee on Copyrights

The University Committee on Copyrights is hereby established and shall have such responsibilities as the Chancellor may specify, including but not limited to the following:

- a. Monitor trends in such areas as institutional copyright use policies, changes in copyright ownership models, and guidelines for fair use information;
- b. Identify areas in which policy and guideline development or revisions are required, and make recommendations to the Chancellor;
- c. Cooperate with the administration to propose university policies and guidelines regarding ownership and use of copyrighted or licensed scholarly works;
- d. Assist in identifying educational needs of the faculty and others related to compliance with

- copyright policies and guidelines, and advising on appropriate ways to address those needs; and
- e. Under procedures specified herein, hear and recommend resolution of disputes involving copyright ownership.

The committee shall consist of 13 members: representatives of the student body, EPA-non-teaching employees, SPA employees, the libraries, the Office of the University Attorney, the Office of Technology Transfer, the Copyright Management Officer, the Vice Chancellor for Research and Graduate Studies or designee who shall chair the Copyright Committee, and five faculty members who will be elected by the Faculty Senate. Student representatives shall serve for one-year renewable terms. Other representatives shall serve for three-year renewable terms.

7. Copyright Management Officer

The position of Copyright Management Officer is hereby established to advise faculty, EPA-non-faculty employees, SPA employees, and students who have fair use and copyright permission questions related to university business or student works.

The Copyright Management Officer's duties shall also include the following:

- a. Assist in identifying educational needs of the campus community related to compliance with copyright policies and guidelines, and advising on appropriate ways to address those needs;
- b. Serve as a member of the University Committee on Copyrights.
- 8. Works Subject to Both Copyright and Patent Protection

Works subject to protection under both patent law and copyright law shall be reviewed by the Office of Technology Transfer and the University Committee on Intellectual Property/Patents. If the university elects to retain title to its patent rights, the inventor/creator shall assign copyright and patent rights to the university. The inventor/creator shall be compensated in accordance with university policy.

9. Disclosure to the University Committee on Intellectual Property/Patents
Whenever faculty, EPA non-faculty employees, SPA staff or students of the university create
copyrightable material which is or may be owned by the university or a third party and which may also
have commercial application, a disclosure of the existence of the material should be made, in writing,
to the University Committee on Intellectual Property/Patents. The written disclosure should be made
as soon as practical prior to or after creation of the work.

10.Dispute Resolution

- a. Jurisdiction
 - Any university faculty, EPA non-faculty employee, SPA staff employee, or student may seek resolution of a dispute regarding fair use or copyright ownership of a work governed by this Copyright Policy, including a dispute over whether use of university resources is an exceptional use, by filing a written request with the Chair of the University Committee on Copyrights. The chair shall appoint a 5-member panel to hear the dispute with 3 panel members being selected from the elected faculty members of the committee. Review of all matters related to copyright shall fall under the exclusive jurisdiction of the University Committee on Copyrights, subject to the normal appeal processes.
- b. Conduct of the Hearing

At its discretion, the panel may elect to conduct a hearing into the matters or may make a recommendation based upon the written record, provided that all parties to the dispute are given an opportunity to present evidence and arguments in support of their respective positions. The panel will make every effort to mediate these matters prior to any hearing. Each party shall

provide the other party with a copy of any written materials submitted to the panel simultaneously with submission of such materials to the panel. Any hearing will be conducted following procedures set forth in writing by the panel or promulgated by the University Committee on Copyrights. No party shall have the right to be represented by counsel before the panel, but any party may be accompanied at a panel hearing by an advisor of his or her choosing, who shall not participate in the hearing.

c. Disposition

Each panel shall report its written findings, conclusions and recommendations for disposition of the matter to the appropriate Vice Chancellor(s) on behalf of the Chancellor, within forty-five days of appointment of the panel by the Chair of the University Committee on Copyrights. The Chair of the Committee may extend the time period of such report by not more than thirty days for good and reasonable cause. Copies of such findings, conclusions, and recommendations shall be provided to all parties. Upon receipt of such findings, conclusions, and recommendations, the appropriate Vice Chancellor(s) shall issue a written decision in the matter. The decision shall be final, subject to appeal rights under The Code of the University of North Carolina.

III. Ethics in Research and Creative Activity

A. Policy

Faculty, staff, post doctoral fellows and students of East Carolina University have the responsibility to seek honestly and to promulgate ethically the truth in all phases of work. This responsibility governs not only the production and dissemination of research and creative activities, but also all applications for funding, reports to funding agencies, and teaching and publication of teaching materials.

East Carolina University subscribes to the following principles in its research and creative activities:

- 1. Honesty and truth must underlie all professional relationships of faculty, staff, post doctoral fellows and students with those in their profession, the academic community, and the public.
- 2. Fabrication and falsification of information that a researcher claims is based on experimentation or observation are unethical.
- 3. Intentionally selecting data or the treatment of data to present views known by the researcher to be false is unethical.
- Plagiarism, defined here below to include, without limitation, dissemination under one's own name of the tangible products of another person's work without due credit to that person, is not acceptable.
- Other practices that seriously deviate from those that are commonly accepted within the scientific or academic community for proposing, conducting, or reporting research are not acceptable.
- 6. Publication of essentially the same article in more than one journal of a study without citing the duplication is unethical, as is any equivalent duplicity.
- 7. Faculty and staff members must be fully conversant with and able to defend their part in any work disseminated with their permission under their names and should be generally conversant with the said work as a whole. The guidelines of the International Committee of Medical Journal Editors are, in part, that "authorship should be based only on substantial contributions to (a) the conception and design, or analysis and interpretation of data; (b) drafting the article or revising it critically for important intellectual content; and on (c) final approval of the version to be published. Conditions (a), (b) and (c) must all be met. Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is also not sufficient for authorship.
- 8. Faculty and staff members must list co-authors of a work, disseminated in any form, but only with those persons' expressed consent. The unwarranted inclusion of co-authors who have not been substantially involved in the work is unethical and may lead to violations of item 7., above.

- 9. Students completing theses or taking research courses for credit should not be relegated to purely routine work without training or participating in the design of the project or the analysis of the data. Therefore, the involvement of unpaid student assistants in research must be structured to enhance students' education and creative activities. Graduate students must be authors on publications that contain substantial parts of their thesis and/or dissertation. The chair and/or members of graduate student's thesis or dissertation committee should encourage the student to prepare a manuscript(s) for publication based on his or her thesis or dissertation research. If a student prepares a manuscript for publication based on a thesis or dissertation, he or she should be the first author on the resulting publication. Service on a thesis and/or dissertation committee does not in itself entitle a faculty member to co-authorship of a manuscript or an abstract unless the provisions of this section (Section V.A.7 above) are met.
- 10. When it is appropriate for students to participate as subjects in research, faculty and staff must assure potential subjects that participation is absolutely voluntary, that participation as a research subject shall not be a course requirement, that participation shall have educational value, that students shall be told at the beginning of the course if there are to be opportunities for extra credit, that alternative opportunities for extra credit shall be available for students not wishing to participate as subjects in research, and that students may withdraw from participation for extra credit at any time without penalty. (See Principles and Policy for the Protection of Human in Research above.)
- 11. In all cases of research involving human beings or animals, faculty and staff members must be familiar with and adhere to special regulations and issues of ethics and humane treatment associated with research on these subjects. (See *Animal Welfare Regulations* above.)
- 12. Faculty and staff members must comply with all regulations and laws affecting research and publication (including fiscal management, the use of hazardous materials and patents, licensing, technology transfer), whether these be derived from the grantor, the local community, the university, or the state or federal government. An intentional violation of copyright laws or the intentional use of materials, developed by others without permission, is prohibited. All members of the university community have a personal responsibility for implementing this policy in their research and creative activities.
- B. Procedures for Reporting, Investigating, and Determining Penalties for Unethical Activities The university shall investigate substantive allegations of research misconduct in the proposing, conducting, or reporting of research and creative activities with all practical dispatch, with fairness, and with consideration for the rights of the accused and the accuser. The university is obligated to notify all parties affected by such acts, where proven, at appropriate times.

1. Definitions

- a. Allegation: An allegation is any means, any written or oral statement, or other indication of possible research misconduct made to an institutional official.
- b. Claimant: A person or organization alleging that research misconduct has occurred. An individual claimant is also commonly referred to as a "whistleblower", a term preferred by the federal government.
- c. Conflict of Interest: Faculty selected for service on a panel or a committee must be free from conflict of interest due to associations with either a claimant, if an individual, or a respondent. Examples of such associations include, but are not limited to, collaborations, coauthorships or manuscripts, and co-investigation on any grants or contracts.
- d. Deciding Officer: This office is the institutional official who makes final determinations on allegations of research misconduct and any responsive institutional action. This individual is the Chancellor or his/her delegate, who may carry out any responsibility of the Chancellor under this policy to the extent consistent with the Chancellor's delegation.
- e. Finding of Research Misconduct: A finding that:

- There is a significant departure from accepted practices of the relevant research community;
- ii) The misconduct is committed intentionally, or knowingly, or recklessly; and
- iii) The allegation is proven by a preponderance of evidence.
- f. Inquiry: The inquiry is an assessment of supporting materials and information from witnesses and respondent by a faculty panel to determine whether an research investigation is warranted. This may be known as an "allegation assessment" or an "informal inquiry" in some government documents.
- g. Investigation: The investigation is a formal examination and evaluation of all relevant facts to determine if misconduct has occurred, and, if so, to determine the responsible person(s) and the seriousness of the misconduct. The investigation is conducted by a committee of faculty to include at least one member from outside the unit and when deemed necessary by the Vice Chancellor for Research (VCR), from outside the university. Hearings and testimony are to be recorded.
- h. Preponderance of the evidence: This refers to proof by information that, compared with that opposing it, leads to the conclusion that the fact at issue is more probably true than not.
- i. Research: Research is defined as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. For the purposes of this policy, research includes all basic, applied, and demonstration research in all academic and scholarly fields. Research fields include, but are not limited to, the arts, the sciences, liberal arts, applied sciences, social sciences, the professions, and research involving human subjects or animals.
- j. Research Integrity Officer: This officer is the institutional official responsible for assessing allegations of research misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations. This individual is the VCR or his/her delegate, who may carry out any responsibility of the VCR under this policy to the extent consistent with the VCR's delegation.
- k. Research Misconduct: Misconduct that is defined as fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting the results.
 - i) Fabrication is making up data or results and recording or reporting them.
 - ii) Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record. The research record is the record of data or results that embody the facts resulting from the research inquiry and includes, but is not limited to research proposals, laboratory records, both physical and electronic, progress reports, abstracts, theses, oral presentations, internal reports, books, dissertations, and journal articles.
 - iii)Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit.
 - iv)Research Misconduct does not include honest error or differences of opinion.
 - I.Research Record: This record is defined as 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 research 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.
- m. Respondent: A responded is the person against whom an allegation of scientific

- misconduct is directed or the person whose actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.
- n. Retaliation: This refers to any action that adversely affects the employment or other institutional status of an individual that is taken by an institution or an employee because the individual has in good faith made an allegation of research misconduct or of inadequate institutional response thereto or has cooperated in good faith with an investigation of such allegation.

2. Procedures

- a. Principle of Procedure--Every effort will be made to protect the privacy and reputations of those whose allegations of misconduct are made in good faith and of those against whom allegations of misconduct are not confirmed.
- b. Policies and Regulations-Federal and State policies pertaining to the institution's responsibilities for responding to allegations of research misconduct are on file in the office of Sponsored Research and are available for review.
- c.Initiation by an Allegation-If a member of the faculty or other employee of ECU or student is suspected of Research Misconduct, as defined in the ECU Faculty Manual, Policy and Procedures on Ethics in Research and Creative Activities, that person will be reported to the unit's senior administrator unless there is a potential conflict of interest. (Policy and procedures regarding students are described in the ECU Faculty Manual, Academic Integrity Policy may also apply.) Either documentation or the location of documentation and information pertaining to the allegation will be provided. If claimant brings the allegation to the respondent's supervisor and if the supervisor is neither a chair nor a dean, the supervisor will bring the information to the chair or dean for that unit if considered to be substantive. Thus, if discussions between a supervisor and a claimant suggest that the allegation(s) is(are) serious, and neither frivolous nor malicious, the allegations and supporting information will be presented in a timely manner to the chair or dean, not the respondent.
- d. Determination of Procedure-The chair or dean should consult with the Research Integrity Officer before determining whether the allegations may be dealt with informally or require proceeding with the formal steps for making an Inquiry because the allegations are neither frivolous nor malicious and are deemed substantive. The chair or dean will determine whether and what form of misconduct is alleged to have occurred, what parties are involved or may be affected by the allegations (i.e., co-authors, collaborators, funding agencies, etc.) and what documentation is needed to pursue the allegation. The chair or dean shall notify the VCR of their course of action (i.e., informal solution or recommendation for an Inquiry) regarding all allegations. If the evidence suggests that an Inquiry is warranted, the VCR will be notified immediately. Only the Vice Chancellor for Research has the authority to convene an Inquiry panel or an Investigation Committee. If human or animal subjects are involved, the chair or dean may ask the Administrative University and Medical Center Institutional Review Board or the Animal Care and Use Committee, respectively, to conduct an audit.
- e. If the allegations meet any of the following conditions, the office of Research Integrity of the Department of Health and Human Services or any other appropriate federal agency, should be notified immediately by the VCR.
 - i) there is an immediate health hazard involved;
 - ii) there is an immediate need to protect Federal funds or equipment;
 - iii) it is probable that the alleged incident is going to be reported publicly;
 - iv) the allegation involves a public health sensitive issue such as a clinical trial;
 - v) there is reasonable indication of a possible Federal criminal violation.
- f. If the allegation is not judged to be frivolous, interim administrative actions will be taken, as appropriate, to protect any Federal funds and the public health, and to ensure that the

- purpose of any Federal financial assistance is carried out. Such actions may include but not be limited to freezing grant or contract accounts, suspending clinical trials or appointing an interim project director.
- g. Protecting the whistleblower The VCR will monitor the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in inquiries or investigations. The VCR will ensure that these persons will not be retaliated against in the terms and conditions of their employment or other status at the institution and will review instances of alleged retaliation for appropriate action. Employees should immediately report any alleged or apparent retaliation to the VCR. Also the institution will protect to the maximum extent possible the privacy of those who report misconduct in good faith. For example, if the whistleblower requests anonymity, the institution will make an effort to honor the request during the allegation assessment or inquiry within applicable policies and regulations and state and local laws, if any. The whistleblower will be advised that if the matter is referred to an Investigation Committee and the whistleblower's testimony is required, anonymity may no longer be guaranteed.
- h. Protecting the Respondent Inquiries and investigations will be conducted in a manner that will ensure fair treatment to the respondent(s) in the inquiry or investigation and confidentiality to the extent possible without compromising public health and safety or thoroughly carrying out the inquiry or investigation. Institutional employees accused of research misconduct may consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) at their own expense to seek advice and may bring the counsel or personal advisor to interviews or meetings on the case.

i. The Inquiry-

- i) The VCR will present to the respondent, in writing, the allegations and a copy to respondent's supervisor or chair. If it is necessary to secure notes, data books, computer data, specimens, drafts of manuscripts, grants, contracts or other materials, these will be collected at the time the letter of notice is given to the respondent. Either the VCR or his/her designee will be responsible for securing these items. All materials will be cataloged, receipts provided to respondent, and secured in a locked storage container appropriate for the materials. The Inquiry will be completed within 60 calendar days from the date of delivery of the letter of notice. If the inquiry cannot be completed in 60 days and Federal funds are involved, then the VCR will submit to the appropriate agency 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 any other necessary steps to be taken.
- ii) The Inquiry Panel shall consist of three faculty without administrative appointment or conflict of interest. At least one person shall be from outside the department of the respondent. If respondent is a member of the School of Medicine, the Associate Dean for Research will be consulted by the VCR prior to selecting faculty for an Inquiry panel. All will have sufficient expertise to review the materials and interview witnesses and respondent. The VCR will present the allegations to the panel, review ECU policy and procedures, any special requirements for an affected awarding agency, and establish a time line for conducting the inquiry. The panel will decide for itself which materials to review, which individuals to interview and their order. The Inquiry panel will not receive unsolicited input from faculty or staff except through the VCR. Questions regarding the Inquiry will be referred to the VCR. Refusal to answer questions or otherwise cooperate with an Inquiry or a Research Misconduct Investigation may be used as evidence against the respondent. If the panel finds substantiation of any one allegation, this will be reported immediately to the VCR in writing. It is neither necessary nor desired to proceed through a list of allegations once substantiation of one allegation is established by the Inquiry panel. The function of the Inquiry Panel ends with its written report.
- iii) The written inquiry report will be prepared by the panel which consists of the name and

- title of the panel members; the allegations; the PHS support; a summary of the inquiry process used; a list of the 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.
- iv) The VCR 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 portions of the draft inquiry report that address the claimant's role and opinions in the investigation. Within 14 calendar days of their receipt of the draft report, the claimant and respondent will provide their comments, if any, to the inquiry committee. Any comments that the claimant or respondent submits on the draft report will become part of the final inquiry report and record. Based on the comments, the inquiry committee may review the reports as appropriate. If respondent is from the School of Medicine, a copy of the report will be give to the Associate Dean for Research, also. If review of the materials and interviews fail to confirm the allegations, a description of the inquiry process and the finding will be reported in writing to the VCR. The VCR will inform all affected parties of the finding, including respondent, claimant, respondent's chair, dean and any other parties informed of the inquiry. The VCR will expunge any reference to the allegations from respondent's personnel file.
- v) If the Vice Chancellor for Research, in consultation with the Vice Chancellor for Academic Affairs or Vice Chancellor for Health Sciences, decide that an investigation should be conducted, the VCR will notify the appropriate federal or non-federal agency and will provide them with a copy of the final inquiry report and the institution's policies and procedures for conducting investigations.
- vi) If Federal funds are involved and the inquiry is terminated prior to completion of all the steps required by the appropriate agency, the VCR will notify that agency of the planned termination and the reasons therefore.
- vii) A detailed documentation of the inquiry, regardless of its outcome, will be kept in the VCR's office for at least five years following completion of the report and will provide copies of this report to any authorized sponsoring agency upon written request of that agency.
- j. Additional Procedures if Externally Funded Activities are Involved--The Vice Chancellor for Research will be responsible for informing the funding agency that an Inquiry involving one of their grants or contracts is being initiated. When the findings of the Inquiry Panel are given to the VCR, the appropriate information will be relayed to the funding agency. Since different Federal and State agencies have different regulations which change over time, it is imperative that the VCR assure that the Inquiry and any subsequent investigation meet the funding agency's requirements.
- k.The Investigation--A determination that substantive evidence exists supporting allegations of research misconduct necessitates a formal Research Misconduct Investigation to begin within 30 calendar days of the Inquiry Panel's written report. All appropriate sponsors will be notified immediately that an investigation will be performed. The investigation will be completed and a report submitted to the appropriate sponsoring organization within 120 calendar days of the committee's formation. If the investigation cannot be completed in 120 days and Federal funds are involved, then the VCR will submit to the appropriate agency 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 any other necessary steps taken to date. That the respondent voluntarily leaves or admits guilt does not suffice to terminate the process.
- i) The Investigation Committee shall consist of five faculty without administrative appointment or conflict of interest, including not more than 2 members from respondent's department and at least 1 member from outside the unit (College or School) or the university, all of whom shall have the necessary expertise to evaluate the evidence and issues related to the allegations, interview the principals and key witnesses and conduct the investigation. If the allegations pertain to a project funded by an external source, one committee member must be from

- outside the university. If respondent is from the School of Medicine, the Associate Dean for Research will be consulted prior to selection of the committee. The VCR is responsible for charging the panel, including: review of all allegations, this appendix and related university documents that may have a bearing on the investigation, results of the Inquiry Panel and what documentation is available and setting a schedule to complete the investigation within 120 calendar days. If external funds supported the project, then the VCR will communicate progress on the investigation to the funding agency. Documents and specimens will remain secured. All participants must bear in mind that when external funding, human subjects or animal subjects are involved there is the potential for criminal charges being filed and a "chain of evidence" must be maintained: anyone wishing to remove materials from storage must obtain the permission of the VCR and must sign for each item removed.
- ii) The Investigation Committee, with advice from the VCR, will decide on the order of presentation of materials and witnesses and schedule one or more hearings. All documentary evidence presented to the committee by the VCR will be made available to respondent at least 10 working days before the hearing. Legal advice shall be provided by the university for the committee. The hearings shall be closed to the public. The respondent shall have the right to be present during presentation of the evidence to the committee. The respondent shall also have the right to an advisor, to present the testimony of witnesses and other evidence, to confront and cross examine witnesses. The respondent's advisor does not have any right to cross examine witnesses. The Chair of the committee has the discretion at any time to allow respondent's advisor to have an active role in the hearing, either by directly questioning witnesses or by submitting questions in writing through the Chair, or to restrict the advisor to advising the respondent only. An audio recording of all hearings will be made and minutes prepared to be included with the committee's report: both the chair of the committee and respondent will sign the minutes in order to indicate that the minutes accurately represent the proceedings during the hearing. The committee needs to determine whether a preponderance of the evidence exists supporting a Finding of Research Misconduct, as defined by the Policy on Ethics in Research and Creative Activities, has occurred. (Note: This is a less stringent standard than "clear and convincing evidence" and less stringent than "beyond any reasonable doubt.") When the committee has made its determination, a written report will be given to the VCR that describes both the process and the findings of the investigation.
- iii) Where federal funds are involved and the investigation is terminated prior to completion of all steps required by the appropriate agency, the VCR will notify the agency of the planned termination and the reasons therefore.
- iv) Upon initiation of an investigation, interim administrative action will be taken, as appropriate, to protect any Federal funds and the public health, and to insure that the purpose of any Federal financial assistance are carried out. Such action may include but not be limited to freezing grant or contract accounts, suspending clinical trials or appointing an interim project director.
- I. Completion of the Investigation--When the Investigation Committee has completed its investigation, it will prepare a draft report; and this report, along with minutes of all hearings and tape recordings of the hearings and recommendations will be given to the VCR. If respondent is from the School of Medicine, a copy of the draft report will be given to the Associate Dean for Research.
 - i) The report must describe the policies and procedures under which the investigation was conducted, describe how and from whom information relevant to the investigation was obtained, state the findings, and explain the basis for the findings. The report should include the actual text or an accurate summary of the views of any individual(s) interviewed.
 - ii) The VCR will provide the claimant, if he or she is identifiable, with those portions of the draft investigation report that address the claimant's role and opinions in the investigation. The report should be modified, as appropriate, based on the claimant's comments.

- iii) The draft report will also be given to the respondent for comment and review. If the respondent elects to provide a rebuttal, he or she must do so within 10 calendar days. The respondent may rebut orally or in writing, and these responses will become part of the permanent record.
- iv) 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.
- v) In distributing the draft report, or portions thereof, to the respondent and claimant, the VCR 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 VCR may request the recipient to sign a confidentiality statement or to come to his or her office to review the report.
- vi) If the committee makes a Finding of Research Misconduct proven by a preponderance of evidence to have occurred in violation of the principles set forth in this policy, the committee may include recommendations for sanctions.
- vii) If the respondent provides a rebuttal to the evidence for the VCR, the VCR may submit this information to the committee and may request additional deliberations or recommendations from the committee. After deliberation, or if no timely response is received, the committee shall issue its final written report to the VCR. If the VCR disagrees with one or more aspects of the report, the VCR may submit a separate report, but may not modify the committee's report without explicit permission by the majority of committee members. In addition to the findings of the committee, the VCR's report will include recommendations with respect to notification of any journals or other publications with already published or pending publications which are deemed relevant, collaborating institutions or individuals, awarding agencies, and any other individuals or agencies judged to "need to know" in order to avoid further consequences of potentially misleading or fraudulent information. These reports and any rebuttal provided by respondent will be given to the Chancellor and to the appropriate vice chancellor for action as provided herein below. If respondent is from the School of Medicine, copies of these reports and any rebuttal will be given to the Associate Dean for Research.
- viii) If the committee finds insufficient evidence of fraudulent or unethical behavior in violation of the principles set forth in this policy, the chair of the committee shall notify the VCR who shall immediately notify all individuals and groups involved that the charges have been dismissed; and every attempt will be made to clear the public and private record of the respondent including letters to be sent to all awarding agencies, journals or others who had been informed that a formal inquiry process had been initiated.
- ix) Investigative offices of Federal agencies will be notified promptly by the VCR as and to the extent required by applicable law regulation, to include:
 - a. if at any time during the investigation there is reasonable indication of possible criminal violations.
 - b. if there are any developments which disclose facts that may affect present or potential funding for the respondent, and
 - c. of the final outcome of the investigation.
- x) The detailed documentation to substantiate the findings of the investigation will be maintained for at least five years after the final report is delivered to the VCR or Federal agencies. The report to Federal or other external awarding agencies will include a description of the process used to arrive at the findings within the report.
- m. Prohibition of Expenditure of Funds-If there are any developments during any time of the investigation which disclose facts which suggest that specific funds from awarding agencies are not being expended in an appropriate fashion, a recommendation by the committee to the VCR may be forwarded to the appropriate vice chancellor that the university prohibit further expenditures of these funds pending final outcome of the Research Misconduct Investigation.

- n. Action by the Appropriate Vice Chancellor
 - i) The appropriate vice chancellor, after consultation with respondent's dean and VCR, shall determine what disposition to make of the case. The determination shall be transmitted to the respondent promptly. If the vice chancellor determines that the case has not been proven, the vice chancellor may either ask the VCR to provide more information or dispose of the case as in Section V.B.2.i.2. above with the VCR to notify all affected parties that the charges have been dropped. If the vice chancellor chooses this latter action, a written rationale for disposing of the case must be provided by the vice chancellor for the VCR and members of the Investigation Committee.
 - ii) If the appropriate vice chancellor concurs with the reports by the Investigation Committee and the VCR that misconduct has occurred and determines that a sanction will be imposed, the vice chancellor will consult with the VCR and respondent's dean regarding recommendations for appropriate sanction(s), to include but not limited to, censure, suspension from employment, reduction in rank, removal of tenure, or dismissal and will proceed in accordance with the ECU Faculty Manual. Whether or not sanctions are imposed on the respondent, the vice chancellor may prescribe corrective action responsive to the alleged misconduct and take other appropriate action including the recommended notifications of journals, funding agencies and other affected parties by the VCR. The VCR shall notify respondent's dean in reference to sanctions or other actions imposed.
 - iii) Respondent may appeal imposition of sanctions through the appropriate appellate committee as described in the ECU Faculty Manual, Appendix D, Tenure and Promotion Policies and Procedures of East Carolina University or, if discharge or serious sanctions are not imposed, through ECU Faculty Manual, Appendix Y.