PART VII

RESEARCH INFORMATION
PART VII
RESEARCH INFORMATION

CONTENTS

I. Policy and Guidelines for External Funding (Formerly Appendix O)
   A. Introduction
   B. Policy Statement
   C. Exceptions
   D. Definitions
   E. Clearance Procedures for Contracts, Grants, and Cooperative Agreements
   F. Clearance Procedures for Soliciting Gifts
   G. Acceptance of Gifts
   H. Recording, Acknowledgment, and Disposition of Gifts
   I. Maintenance of Prospect and Resource Files
   J. Preparation of Fund-Raising Literature
   K. Scheduling of Fund-Raising Activity
   L. Budget Information for Fund-Raising Projects
   M. Involvement of Volunteers in Fund-Raising Efforts
   N. Public Statements Regarding Gifts
   O. Special Projects By Non-university Related Organizations

II. Patent Procedures
    A. General
    B. Responsibilities of University Personnel
    C. Publication and Public Use
    D. Requests for Waiver of University Rights by the Disclosing Party
    E. Revenue Sharing
    F. Administration

III. Copyright Policy
    A. Introduction
    B. Scope and Coverage
    C. Definitions
    D. Use of Copyrighted Works
    E. Copyright Ownership
    F. Administration
    G. Dispute Resolution

IV. Principles and Policy for the Protection of Human Subjects of Research (Formerly Appendix R)
    A. Statement of Ethical Principles
    B. Institutional Policy
    C. Implementation of Policy

V. Animal Care and Use in Research and Instruction (Formerly Appendix S)
    A. Policy
    B. Responsibilities

VI. Policy and Procedures on Ethics in Research and Creative Activities (Formerly Appendix U)
    A. Policy
    B. Procedures for Reporting, Investigating, and Determining Penalties for Unethical Activities

VII. Policy on the Custody, Retention, Transfer and Access to Research Data and Records
I. Policy and Guidelines for External Funding (Formerly Appendix O)

A. Introduction
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, it is necessary to seek grants and contracts from governmental and other sources and to obtain gifts from alumni, friends, corporate entities, and foundations.

B. Policy Statement
The basic principle affirmed in this policy statement is that East Carolina University’s external funding policy shall be centrally coordinated but structured to accommodate individualized and decentralized fund-raising activities. 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 solicitation. Therefore, with the exceptions noted below, no formal request for external funding shall be made by any university employee in the name of or for the benefit of the university without prior clearance through the Office of Institutional Advancement or the Office of Sponsored Programs.

C. Exceptions
The East Carolina University Educational Foundation (Pirate Club) and the East Carolina University Medical Foundation shall be exempt from the policies and reporting procedures stated in this document where private gifts which clearly entail no contractual obligations by ECU of direct benefit to the contributor are involved. (See “Definitions” for clarification of the term “gift” as used in this policy statement.) Any uncertainty in this regard shall be resolved by discussion with the vice chancellor for institutional advancement. In order that each university fund-raising program may achieve maximum results, it is anticipated that all foundations will communicate with each other and coordinate their activities.

D. Definitions
Terms used in this policy statement are defined below.

1. Gift
A gift is an item of value, ownership of which is voluntarily transferred from one party to East Carolina University or one of its 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 may also be classified as unrestricted (i.e., use or disposition of the gift is at the discretion of the university) or restricted (i.e., use is limited to certain activities, departments, beneficiaries, etc.).

Examples of restricted gifts are sums of money which are used to finance building projects, create scholarship funds, or establish individual scholarships and items of equipment which are designated for use only in certain activities or by specific departments or schools. Where cash or property-in-kind is given in response to a proposal for a specific project, the transaction should be considered as a gift when the donor is an individual or a for-profit commercial enterprise, and as a grant when the donor is a governmental agency or private nonprofit foundation or organization. Gifts or grants of cash or property-in-kind from foundations (corporate foundations) which remain under the financial control of the for-profit corporation should be classified as gifts. A proposed “gift” by a for-profit commercial enterprise which is contingent upon ECU or one of its units conducting specified research or providing other specified services which redound to the direct benefit of the commercial enterprise should not be considered as a gift, but should be considered and treated as a contract to be coordinated with the office of Sponsored Programs as outlined below. Occasionally, it may seem advantageous to combine an agreement to conduct specified research or provide other specified services on behalf of a commercial enterprise with an understanding that the commercial enterprise will make a gift of cash or equipment to the university which may be restricted to use by a specific school, department, or individual. Such arrangements are fraught with legal and ethical problems and should be thoroughly discussed with the office of Institutional Advancement before any commitments are made.

2. Contract
In general, a contract is given for a project where the funding agency has already identified the need, determined the type of activity required to meet this need, identified the expected outcomes for the project, selected an acceptable cost range, and estimated the time required to complete the project. Often, the funding agency merely chooses the best among several candidates to carry out the project and may exert fairly strict management control over the contract recipient. Contracts are typically awarded by the federal government in response to requests for proposals (RFPs), by state and local government agencies, and by for-profit commercial entities (single owner companies, partnerships, and corporations). Unsolicited proposals, i.e., proposals submitted on the initiative of the would-be principal investigator or project director rather than in response to an RFP, may also result in a contract. In most cases, progress reports, a final report, and a financial report are required by the sponsor, and the project is in most cases subject to audit. From the sponsor’s point of view, contracts are typically entered into to produce a specific product (often simply a report or service) which is of direct benefit to the sponsor. Typical contracts with commercial firms entered into by the university in recent years include environmental impact studies, clinical drug studies, field
testing of psychological questionnaires, and internship agreements for psychology and allied health students. Typical contracts with government agencies include the conduct of specific research and/or development for various federal government departments, the provision of health and educational services for a number of state government departments, and the provision of student internships to various local government units.

3. Grant
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. In general, grants are characterized by greater latitude in shifting funds among budget categories, more flexibility in the timetable necessary for completing various elements of the project, and more freedom in the methods used to accomplish the intended outcome. Grants are typically awarded by the federal government and by private nonprofit foundations and organizations. In most cases, a final report and a financial report are required, and the project is often subject to audit. In the case of small grants (usually with a specified limit of typically $10,000-15,000), reporting requirements are often reduced or eliminated entirely.
Outcomes of the project are typically not of direct benefit to the sponsor of a grant.

4. Cooperative Agreement
A cooperative agreement shares some of the attributes of both the traditional relationships, but is more like a contract than a grant. The funding agency retains an interest in procedures, timetables, etc. and works cooperatively with the awardee so as 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.

E. Clearance Procedures for 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 activities to be conducted by any faculty or staff member or other person associated with the university shall be coordinated in advance of submission with the Office of Sponsored Programs and submitted in accordance with the policy and procedure statements set forth in the ECU BUSINESS MANUAL.

This policy applies irrespective of which ECU office or ECU-affiliated agency may ultimately administer the funded grant, contract, or cooperative agreement. It does not apply to preliminary or informal inquiries, whether oral or written, to determine whether a potential sponsor may be interested in considering a proposal for a certain project. However, the policy does come into effect when such inquiries result in encouragement from the potential sponsor to submit a letter or a written proposal or when the inquiries proceed to a point where commitments or funding levels are discussed. The importance of following the procedures referred to above whenever university personnel, facilities, equipment, or supplies are to be employed cannot be overemphasized.

F. Clearance Procedures for Soliciting Gifts
Faculty or staff members who wish to undertake any type of fund-raising project shall contact their department or unit head, dean, or vice chancellor, as appropriate, concerning the appropriateness of the proposed project and its adherence to department, division, and university priorities. At the same time, they are encouraged to contact the Office of Institutional Advancement to discuss the idea and its possibility for funding. Once a project has been approved through the originator's division, the originator shall send a memorandum to the Office of Institutional Advancement containing, as a minimum, the following information:
1. the purpose for which the solicitation will be made,
2. the amount of money or type of gift to be requested,
3. the name(s) of any known prospect(s) (individual, corporate, or foundation) suggested for solicitation,
4. the approximate date recommended for solicitation, if appropriate, and
5. a statement to the effect that the project has been approved by the originator's division

In evaluating the proposed solicitation, the Office of Institutional Advancement will attempt to identify potential sponsors in addition to the prospect(s) suggested by the originator of the project. The Office of Institutional Advancement will consider each prospect's university affiliations, other interests, past giving record, past and present solicitation activity, and specific project interest, if known.

Clearance through the Office of Institutional Advancement of the solicitation will be given in writing outlining the level of involvement by the Office of Institutional Advancement and the individual or department submitting the request. For example, the entire solicitation project might be conducted by the Office of Institutional Advancement; or a particular faculty member or dean and a support group, such as the Friends of the Library, may be authorized to conduct the project; or a combined effort with joint solicitation calls by members of the Office of Institutional Advancement, key faculty members, and/or volunteers may be endorsed.

Postponement by the Office of Institutional Advancement of the project will also be given in writing with the reason(s) for the decision. The vice chancellor for institutional advancement will be available to discuss the postponement, the relative priority of the project, and rescheduling the solicitation with the sponsor and his or her vice chancellor.
G. Acceptance of Gifts
Acceptance of a gift--whether in cash or in kind--imposes a legal obligation to comply with the terms established by the donor. Therefore, it is necessary that the nature and extent of this obligation be clearly understood. For this reason, the terms of each restricted gift will be reviewed to ensure that they do not hamper the usefulness or desirability of the gift to ECU. If a gift is deemed unacceptable because of the restrictions the donor has placed on its use, the donor will be requested to remove or modify the restrictions, as appropriate. A gift will be refused or returned when it
1. is determined to be for a purpose inappropriate or not in the best interest of ECU or
2. would obligate ECU to undertake responsibilities, financial or otherwise, which it may not be able or willing to meet for the period required by the terms of the gift.

Gifts-in-kind will be reviewed with special care to assure that acceptance will not involve excessive financial commitments or other obligations disproportionate to the usefulness or value of the gift. Consideration will be given to such factors as the cost of maintenance, cataloging, delivery, insurance, display, and space requirements for exhibition or storage.

When gifts-in-kind are given to ECU with the intent of the donor to receive a tax deduction, it shall be the responsibility of the donor (not ECU) to obtain an appraisal establishing the value of the gift for tax purposes. ECU shall not become involved in the appraisal process, as such involvement could result in the appraisal's accuracy and objectivity being challenged by the Internal Revenue Service.

H. Recording, Acknowledgment, and Disposition of Gifts
It shall be the responsibility of the Office of Institutional Advancement gift records office to officially record and receipt all gifts, including cash, pledges, securities, trusts, insurance policies, real estate, and other gifts-in-kind to East Carolina University or any agency thereof. Therefore, all gifts shall be processed through the gift records office, where they will be entered on the central donor file and a receipt issued before any gift is deposited in any university account, transferred to any unit's property record, or otherwise disposed of. Gifts-in-kind will become the property of East Carolina University or one of its foundations, as appropriate, and will be handled, inventoried, and/or disposed of in accordance with applicable policies and procedures.

Official acknowledgment of gifts to the university shall be coordinated through the Office of Institutional Advancement. The chancellor will acknowledge all major gifts. Other principals in a particular gift transaction are also encouraged to express their personal gratitude or the appreciation of their department or school and are requested to forward a copy of their letter to the Office of Institutional Advancement for the central donor file.

I. Maintenance of Prospect and Resource Files
It shall be the responsibility of the Office of Institutional Advancement to establish and maintain prospect and resource files for the purpose of providing timely and relevant information about prospective individual donors, private foundations, and corporations. To assist in the fulfillment of this responsibility, each solicitation or cultivation contact (where specific information is gained that will be of use in future solicitation attempts) with a prospect or donor by any representative or agent of the university shall be reported to the Office of Institutional Advancement on a call report form, which identifies the purpose of the contact, the major points of discussion, and the recommended action(s) to maximize the benefit of the contact. Call report forms will be made available by the Office of Institutional Advancement.

J. Preparation of Fund-Raising Literature
All literature, including brochures, booklets, and letters, used to attract private funds to ECU shall be coordinated through the Office of Institutional Advancement in order to ensure that the most accurate information appropriate to a particular fund-raising effort is reflected.

K. Scheduling of Fund-Raising Activities
It shall be the responsibility of the Office of Institutional Advancement to establish and maintain a master calendar which incorporates the schedule of all mailings, solicitations, and other fund-raising activities to ensure the potential for maximum success for each.

L. Budget Formulation for Fund-Raising Projects
The formulation of budgets which are to be spent for private fundraising projects in the name of the university shall be the joint responsibility of the vice chancellor for institutional advancement and the appropriate individual or group representing the project.

M. Involvement of Volunteers in Fund-Raising Efforts
Whenever volunteers are to be involved in fund-raising efforts, it shall be the responsibility of the Office of Institutional Advancement to assist in the selection and recruitment of the volunteers and to assist in their training in order for them to be more effective in soliciting funds.

N. Public Statements Regarding Gifts
It shall be the responsibility of the ECU News Bureau, in conjunction with the Office of Institutional Advancement, to initiate the preparation of all public statements concerning gifts to the university or to any of its units. Project sponsors and other appropriate individuals will be asked to supply pertinent information and will be involved in coordinating the public announcement.

O. Special Projects by Non-university Related Organizations

The university neither encourages nor endorses the use of the East Carolina University name by non-university related organizations to solicit funds, even though a portion of the funds to be raised may come to the university. To avoid embarrassment and possible legal problems, it is emphasized that any individual or organization not directly affiliated with the university should coordinate with the vice chancellor for institutional advancement in advance any plans for fund-raising activities involving the name of the university.

Approved: 17 February 1984
East Carolina University Board of Trustees

II. Patent Procedures of East Carolina University

A. General

1. As defined by the patent and copyright policies of the Board of Governors, to which these procedures are expressly subject, East Carolina University has an interest in all inventions of University personnel (Disclosing Party) that are conceived or first actually reduced to practice as a part of or as a result of University research, activities within the scope of the Disclosing Party’s employment by the University, or activities involving the use of University time, facilities, staff, materials, University information not available to the public, or funds administered by the University.

2. The University may also have an interest in inventions under the terms of contracts, grants, or other agreements. Faculty, staff, and students whose inventions are made on their own time and without University facilities, materials, or resources and which inventions are, therefore, their exclusive property as specified by the patent and copyright policies may avail themselves of the opportunity to submit the invention to the University for consideration of possible patenting and/or commercial exploitation and management under terms to be agreed between the Disclosing Party and the University.

3. The provisions of the patent procedures are subject to any applicable laws, regulations, or specific provisions of the grants or contracts, which govern the rights in inventions made in connection with sponsored research.

4. Under the terms of certain contracts and agreements between the University and various agencies of government, private and public corporations, and private interests, the University is or may be required to assign or license all patent rights to the contracting party. The University retains the right to enter into such agreements whenever such action is considered to be in the best interest of the University or the public. Ordinarily the University will not agree to assign rights in future inventions to private corporations or businesses.

B. Responsibilities of University Personnel

1. University personnel who, either alone or in association with others, make and/or conceive an invention within the scope of their University employment, in which the University has or may have an interest, shall disclose such inventions in a timely manner on forms provided for this purpose by the Office of Technology Transfer \[http://www.research2.ecu.edu/ott/inventors/inventors1defaul.htm\]. The Office of Technology Transfer will promptly acknowledge its receipt of completed disclosure forms and will distribute such forms as soon as practicable to the University Patent/Intellectual Property Committee (Committee) for consideration. The Committee will strive to preserve the right to timely publication by faculty.

The Committee will review each written disclosure promptly. The Disclosing Party or his or her representative shall be allowed to examine all written materials submitted to the Committee in connection with his or her disclosure and to make a written and, where practical, oral presentation to the Committee. The Committee will decide on the proper disposition of the invention to secure the interest of the University, the Disclosing Party, the sponsor, if any, and the public. The Committee’s decision may include, but is not limited to, one or a combination of the following:

a. to submit the disclosure for review by a patent or invention management firm;

b. to make inquiries of potential licensees that may have an interest in the invention, including the financing of a patent application, where applicable;

c. to study the practicality of applying for a patent with available University resources;

d. in proper cases, to release its rights to the Disclosing Party subject to an agreement to protect the interests of the University, the sponsor if any, and the public, including an obligation to pay to the University a percentage of future royalties; and

e. to dedicate the invention to the public.

The Committee will strive to review and consider the merits of each disclosure as soon as practicable given the circumstances surrounding the disclosure, but not longer than within three months from the time of disclosure to the

University. The Disclosing Party will be notified in writing of the decision of the Committee on (1) the equities involved including financial participation, (2) whether the University plans to file a patent application, or (3) whether the University will accept assignment of the invention for patenting, licensing and/or commercial handling as applicable. If the University chooses neither to file a patent application or otherwise make available commercially nor to dedicate to the public an invention in which it asserts its rights, the invention, at the Committee’s discretion, may be released in writing to the Disclosing Party, with the permission of the sponsor, if any.

If, after the University has filed a patent application, it decides to abandon the patent, the Disclosing Party will be promptly notified in writing, and all rights at the Committee's discretion may be released by written agreement to the Disclosing Party, with the permission of the sponsor, if any.

In those cases in which the University has obtained a patent without obligation to sponsors and, if no arrangement has been made for commercial development within a reasonable period from the date of the issuance of the patent, the Disclosing Party may request in writing a release of the University's patent rights. The Committee will promptly either grant the request or will advise the Disclosing Party of the University's plans for the development of the invention.

As to any invention in which the University has an interest, the Disclosing Party, upon request, shall execute promptly all contracts, assignments, waivers, or other legal documents necessary to vest in the University or its assignees any or all rights to the invention, including complete assignment of any patents or patent applications relating to the invention.

2. University personnel may not:
   a. sign patent agreements with outside persons or organizations which may abrogate the University's rights and interests as stated in the patent policy or as provided in any grant or contract funding the invention or
   b. without prior authorization use the name of the University or any of its units in connection with any invention in which the University has an interest.

C. Publication and Public Use
   The University strongly encourages scholarly publication of the results of faculty and student research. Though the patent and copyright policies do not limit the right to publish, except for short periods of time necessary to protect patent rights, publication or public use of an invention constitutes a statutory bar to the granting of a United States patent for the invention unless a patent application is filed within one year of the date of first publication or public use. Publication or public use also can be an immediate bar to patent ability in many foreign countries.

   In order to preserve rights in unpatented inventions, it shall be the duty of the Disclosing Party, or of his or her supervisor, if the Disclosing Party is not available to report immediately to the Office of Technology Transfer any publication, submission of manuscript for publication, sale, public use, or plans for sale or public use, of an invention. All disclosures of a University invention or unpublished research data supporting an invention to non-University individuals or organizations shall be preceded first by execution of a confidentiality agreement and/or materials transfer agreement through the Office of Technology Transfer. In all instances a written record shall be maintained containing the date and extent a disclosure was made, the name and address of the person to whom the disclosure was made, and the purpose of the disclosure.

   After disclosure to the Committee, the Disclosing Party shall promptly notify the Office of Technology Transfer of the acceptance for publication of any manuscript describing the invention or of any sale or public use made or planned by the Disclosing Party.

D. Requests for Waiver of University Rights by the Disclosing Party
   If the Disclosing Party believes that the invention was made outside the general scope of his or her University duties and does not choose to assign the rights of the invention to the University, the Disclosing Party shall, in the invention disclosure, request that the Committee determine the respective rights of the University and the Disclosing Party in the invention and shall also include in the disclosure information on the following points:
   1. the circumstances under which the invention was made and developed;
   2. the employee's official duties at the time of the making of the invention;
   3. whether he or she requests waiver or release of any University claims or acknowledgment that the University has no claim;
   4. whether he or she wishes a patent application to be prosecuted by the University, if it should be determined that an assignment of the invention to the University is not required under the patent and copyright policies; and
   5. the extent to which he or she would be willing voluntarily to assign domestic and foreign rights in the invention to the University if it should be determined that an assignment of the invention to the University is not required under the patent and copyright policies.

E. Revenue Sharing
   1. The University shall share revenue, which it receives from patents or inventions with the Disclosing Party. As noted in the section above, specific provisions of grants or contracts may govern rights and revenue distribution regarding inventions made in connection with sponsored research; consequently, revenues the University receives from such inventions may be exclusive of payments of revenue to sponsors or contractors. Moreover, the University may contract with outside persons or organizations for the obtaining, managing, and defending of patents, and any revenue contractually committed
to such persons or organizations may be deducted before revenues accrue to the University, unless a license agreement otherwise specifies reimbursement of such expenses by the licensee.

2. The Office of Technology Transfer shall strive to require the licensee to pay for all past, present, and future patent expenses, in addition to negotiate fees and/or royalties for each invention. All remaining revenues after payment of these expenses (net income) (per the preceding paragraph) shall be distributed to the disclosing party in a manner consistent with the University License Income Distribution Policy, which can be found at [http://www.research2.ecu.edu/ott/inventors/incomedistrib.htm](http://www.research2.ecu.edu/ott/inventors/incomedistrib.htm) but in an amount no less than a distribution of 50 percent of the first $100,000 net and 25 percent net thereafter. Applicable laws, regulations or provisions of grants or contracts may, however, require that a lesser share be paid to the Disclosing Party. In no event shall the share payable to the Disclosing Party in the aggregate by the University be less than 15 percent of gross revenues received by the University.

3. To the extent practicable and consistent with State and University budget policies, the remaining revenue received by the University from an invention will be dedicated to research purposes, including research in the Disclosing Party’s department or unit, if approved by the Chancellor upon recommendation of the Committee.

F. Administration

1. The University recognizes that the evaluation of inventions and discoveries and the administration, development, and processing of patents and licensable inventions involve substantial time and expense and require talents and experience that may not be available within the University, therefore the University may contract with non-University third party experts in technology licensing.

2. The Committee shall be represented by at least one representative from each academic school or college. Administrative oversight shall be provided by the Vice Chancellor for Research and Graduate Studies. The Committee shall review and recommend to the Chancellor or his or her delegate changes in these procedures, decide upon appropriate disposition of invention disclosures, resolve questions of invention ownership, recommend to the chancellor the expenditure of license revenues, and make such recommendations as are deemed appropriate to encourage disclosures and assure prompt and effective handling, evaluation, and prosecution of invention opportunities and to protect the interests of the University and the public."

Established by UNC Board of Governors, March 1984

Amended: May 2006
Faculty Senate Resolution #06-15
ECU Board of Trustees

III. Copyright Policy

A. 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.

B. 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.

C. 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 notation, 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, 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: 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.

D. Use of Copyrighted Works

1. Appropriate Use of Copyrighted Works

   The Copyright Act of 1976, as amended (Title 17, U.S. Code), generally protects certain rights and privileges of the copyright owner to exclude others from the right to reproduce and publicly distribute, display or perform a work, as well as revise or prepare a derivative work based upon a copyrighted work, without obtaining permission. As an institution devoted to the creation, discovery and dissemination of knowledge, the University supports the responsible, good faith exercise of full fair use rights contained in the Copyright Act.

2. Fair Use

   The “fair use doctrine” of the Copyright Act allows certain statutory exemptions applicable to academia, recognizing the fundamental non-profit mission of universities to advance and disseminate knowledge for public benefit.

   a. Elements of Fair Use

      Individuals from the University community who wish to make fair use of a copyright work must consider in advance four statutory factors:

      i. Purpose and Character of the Use
The purpose and character of the use, including whether the use is of a commercial nature or for non-profit educational purposes.

ii. Nature of the Work
The characteristics of the work being used, including whether it has been previously published and whether it is factual or fictional.

iii. Amount of Work to be Used
The amount, substantiality and qualitative nature of the portion used in relation to the entire copyrighted work.

iv. Effect on the Market
The effect of the use on the potential market for or value of the work.

b. Procedure for Making Fair Use Determinations
The University Copyright Committee, together with the Office of the University Attorney, shall issue and, as necessary, revise guidelines to assist University faculty, EPA non-faculty employees, SPA staff employees, and students in making fair use evaluations. The Chancellor shall also maintain copyright and fair use resources at the ECU libraries. The Copyright Management Officer shall advise faculty, EPA-non-faculty employees, SPA employees and students regarding fair use determinations pursuant to Section VI.B. hereinafter.

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

1. 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 University and the creator 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:
         1) Release or transfer its right to the creator under an agreement with the creator;
         2) Negotiate with the creator for joint ownership of the work;
         3) Require a shop right for the University’s use of the work;
         4) Require expense reimbursement upon commercialization of the work; and/or
         5) 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.

2. 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.

3. 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.

4. 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:
   a. Sponsored orExternally Contracted Works
Ownership shall be in accordance with Section V.A.3. of this Copyright Policy, Sponsored Works Requiring the University’s Ownership, hereinabove.

b. 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.

c. 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.

F. Administration
1. University Committee on Copyrights
The University Committee on Copyrights is hereby established and shall have the 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. Cooperating 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, hearing and recommending 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.

2. 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.

3. 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.

4. 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.

G. Dispute Resolution
1. 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, who 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.

2. Conduct of the Hearing
In 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.

3. 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.

Approved: Faculty Senate Resolution #02-18, April 2002
ECU Chancellor, May 8, 2002
Office of the President, August 6, 2002

IV. Principles and Policy for the Protection of Human Subjects of Research (Formerly Appendix R)

A. Statement of Ethical Principles
1. East Carolina University has adopted as a guiding statement of ethical principles the three comprehensive principles and three applied requirements 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. Respect for persons, beneficence, and justice are the three basic principles; consent, favorable risk/benefit assessment, and selection of subjects, are the three requirements.
2. In addition, East Carolina University, through its University and Medical Center Institutional Review Board (UMCIRB), has adopted as further guiding principles the following existing code:
   • World Medical Association Declaration of Helsinki: Recommendations guiding Medical Doctors in Biomedical Research Involving Human Subjects, and subsequent revisions
3. In addition, East Carolina University acknowledges and accepts the requirements set forth in Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46) for all applicable DHHS-funded research and, except for the requirements for reporting information to DHHS, and all other human research regardless of source of funding.

B. Institutional Policy
It is the policy of East Carolina University that all activities involving human subjects of research at/or sponsored by the university or its faculty and staff shall be submitted, reviewed, and approved by an appropriately established institutional review board -the UMCIRB. The UMCIRB has the sole authority to adjudicate as to the need for exemption from review, as defined by 45 CFR 46.101(b). These categories for exemption are summarized in the Standard Operating Procedure Manual which is published by the UMCIRB.

East Carolina University has established and maintains in accordance with 45 CFR 46 a university-wide IRB entitled the University and Medical Center Institutional Review Board. This committee (UMCIRB) works in two different functional ways:
1. as a policy-recommending or “policy-making” and appellate body subservient to the chancellor for the protection of the rights of human subjects or research conducted at or sponsored by the university and
2. as a research-review body for human research projects in order to apply determined policies towards the protection of human subjects of research.

The UMCIRB serves presently as the IRB with the responsibility and authority to review all human research
activities at/or sponsored by the university which are regulated by 45 CFR 46 or by the FDA or are sponsored by extramural agencies and also all other activities involving human subjects of research at/or sponsored by the university.

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 Procedure Manual.

C. Implementation of Policy

In all activities including human research subjects, the chairperson of the pertinent department or head of the academic unit is responsible for ensuring that the principal investigator’s research activities are performed according to the institutional statement of principles that includes existing ethical codes and the UMCIRB Standard Operating Procedures as guidelines for protecting the rights and welfare of human research subjects. The IRB shall have 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 subjects according to 45 CFR 46.113. The IRB will provide a report to the investigator, institutional officials, and sponsoring agency. Principal investigators of research studies involving human research subjects must submit a complete protocol, current UMCIRB processing form, informed consent document, and any other study related materials. The appropriate forms, instructions and details related to submission can be obtained through the UMCIRB office. 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.

Investigators are responsible for reporting the progress of UMCIRB-approved research to the Office of the UMCIRB, through the use of a renewal or continuation Internal Processing Form, 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 UMCIRB office, any significant injuries to human subjects or any unanticipated problems which involve risks to the research subjects or others.

Approved: 27 September 1984  
East Carolina University Chancellor

Amended: 27 June 2001  
East Carolina University Chancellor

V. Animal Care and Use in Research and Instruction (Formerly Appendix S)

A. Policy

It is the policy of East Carolina University that animals used in research and teaching will receive humane care at all times. Experiments (teaching or research) involving live, vertebrate animals must be performed by or under the immediate supervision of a qualified biological, behavioral, or medical scientist. Experimentation shall be conducted so as to avoid all unnecessary suffering and injury to the animals. The scientist in charge of the experiment must be prepared to terminate it when continuation may result in unnecessary injury or suffering to the animals.

Procedures involving animals should be designed and performed with due consideration of their relevance to human or animal health, the advancement of biological knowledge, or the good of society. The animals selected for a procedure should be of an appropriate species and quality and the minimum number required to obtain scientifically valid results. Statistical analysis, mathematical models, or in vitro biological systems will be used when appropriate to complement animal experiments and to reduce numbers of animals used.

Proper care of animals, including the avoidance or minimization of discomfort, distress, or pain, is a moral imperative. Lacking evidence to the contrary, investigators should consider that procedures that cause pain in human beings cause pain in other animals. Procedures with animals that may cause more than momentary or slight pain or distress should be performed with appropriate sedation, analgesia, or anesthesia. Surgical or other painful procedures shall not be performed on unanesthetized animals paralyzed by chemical agents. Animals that would otherwise suffer severe or chronic pain or distress that cannot be relieved should be painlessly killed at the end of the experiment or, if appropriate, during the experiment.

The living conditions of animals kept for biomedical purposes should contribute to their health and comfort. The housing, care, and feeding of all animals used for these purposes will be supervised by the university veterinarian. Investigators and other personnel shall be appropriately qualified and experienced for conducting procedures with living animals. Adequate arrangements shall be made for their in-service training, including the proper and humane care and use of laboratory animals.
If it is deemed necessary to waive one of the foregoing principles, the decision should be made with due regard by the scientist to the value of the research and only after review and approval by the Animal Care and Use Committee. Such waivers will not be made where the primary purpose is teaching or demonstration.

B. Responsibilities

The faculty member conducting or supervising the conduct of animal experimentation is ultimately responsible for the humane care and use of the animals involved. The faculty member and the appropriate department chairperson will regularly determine if animal use is adequately justified and humane care consistently provided.

Animal husbandry, disease control, appropriate use of anesthesia, administration of medication for relief of pain and distress, and euthanasia will be conducted as recommended by the university veterinarian. Animal care programs throughout the university will be supervised by the university veterinarian as the representative of the administration.

The university Animal Care and Use Committee will monitor care and use of vertebrate animals at ECU and in off-campus ECU programs. The committee will regularly evaluate animal care practices, facilities, laboratories, research procedures, and teaching practices where animals are involved. The National Institute of Health GUIDE FOR THE CARE AND USE OF LABORATORY ANIMALS is accepted as the standard for optimum animal care and will be used, with USDA regulations, by the committee in the evaluation. The committee, additionally, will review proposals and protocols for all teaching and research projects intending to use vertebrate animals. Proposals and protocols will describe, in detail, methods to be used for animal care and assurance of humane treatment during experimentation. Committee approval is essential prior to initiation of the investigation or demonstration. The vice chancellor for health sciences and dean of the School of Medicine and the vice chancellor for academic affairs will have administrative oversight for vertebrate animal care and use programs. The chairperson of the Animal Care and Use Committee and the university veterinarian will report to the two vice chancellors regarding their respective responsibilities.

In summary, it is the responsibility of the faculty conducting animal studies, the veterinarian providing animal care supervision, and the committee monitoring the program to assure humane treatment of animals. Assurance is required by the public and by the granting agencies that animals will be used responsibly and with every consideration given for elimination of distress and discomfort. The university is committed to providing such responsible use and considerate care for animal subjects of teaching and research activities.

Approved: 21 October 1984
East Carolina University Chancellor

VI. Policy and Procedures on Ethics in Research and Creative Activities (Formerly Appendix U)

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.

4. Plagiarism, defined here as dissemination under one's own name of the tangible products of another person's work without due credit to that person, is not acceptable.

5. 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 Part VII, Section I, Principles and Policy for the Protection of Human Subjects of 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 Part VII, Section II, Animal Care and Use in Research and Instruction 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. Violation of copyright laws or the use of materials, developed by others, for personal profit is unethical. 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 fraudulent or unethical 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 - means any written or oral statement or other indication of possible academic or scientific misconduct made to an institutional official.
   b. Claimant - person or organization alleging that academic 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, co-authorships or manuscripts, and co-investigation on any grants or contracts.
   d. Deciding Officer - means the institutional official who makes final determinations on allegations of academic misconduct and any responsive institutional action. This individual is the Chancellor.
   e. Inquiry - assessment of supporting materials and information from witnesses and respondent by a faculty panel to determine whether an academic investigation is warranted. This may be known as an "allegation assessment" or an "informal inquiry" in some government documents.
   f. Investigation - 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.
   g. Research Integrity Officer - means the institutional official responsible for assessing allegations of academic misconduct and determining when such allegations warrant inquiries and for overseeing inquiries and investigations. This individual is the VCR.
   h. 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 academic misconduct. A research record included, 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.
i. Respondent - means the person against whom an allegation of scientific misconduct is directed or the person who actions are the subject of the inquiry or investigation. There can be more than one respondent in any inquiry or investigation.

j. Retaliation - means 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 scientific 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 academic 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 is suspected of Academic Misconduct, as defined in 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, Part IV, Academic Integrity) 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 must determine 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:

   1. there is an immediate health hazard involved;
   2. there is an immediate need to protect Federal funds or equipment;
   3. it is probably that the alleged incident is going to be reported publicly;
   4. the allegation involves a public health sensitive issue such as a clinical trial;
   5. 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 the privacy of those who report misconduct in good faith to the maximum extent possible. 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 academic or scientific misconduct may, at their own expense, consult with legal counsel or a non-lawyer personal adviser (who is not a principal or witness in the case) to seek advice and may bring the counsel or personal advisor to interviews or meetings on the case.

i. The Inquiry-

   (1) 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,
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 academic misconduct necessitates a formal Academic 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 automatically terminate the process.

(1) The Investigation Committee shall consist of five faculty without administrative appointment and conflict of interest, including not more than 2 members from respondent's department and at least 1

Part VII-17
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 have to 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" will be maintained: anyone wishing to remove materials from storage must obtain the permission of the VCR and must sign for each item removed.

(2) 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 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 clear and convincing evidence exists that academic misconduct, as defined by the Policy on Ethics in Research and Creative Activities, has occurred. (Note: this is a more stringent standard than "preponderance of the evidence," but 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.

(3) 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.

(4) 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.

(1) 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.

(2) 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.

(3) 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.

(4) 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.

(5) 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.

(6) If the committee finds clear and convincing evidence of academic misconduct in violation of the principles set forth in this policy, the committee may include recommendations for sanctions.

(7) 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. If respondent is from the School of Medicine, copies of these reports and any rebuttal will be given to the Associate Dean for Research.

(8) 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.

(9) Investigative offices of Federal agencies will be notified promptly:
(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.

(10) 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 Academic Investigation.

n. Action by the Appropriate Vice Chancellor-
(1) 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.

(2) 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 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 of sanctions or other actions imposed.

(3) 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.
VII. Policy on the Custody, Retention, Transfer and Access to Research Data and Records

PURPOSE

The preparation and retention of accurate and appropriate records is essential for a credible research endeavor. East Carolina University, its faculty, its staff, and its 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.

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.)

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.

CUSTODY OF RESEARCH DATA AND RECORDS

By tradition, and for practical reasons, custody of original research data and records shall be with the senior investigator of a project, usually a faculty member. This senior investigator (the responsible investigator) shall insure 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, they should 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, Economic Development and Community Engagement (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 to discuss the responsibilities of data management and retention with other members of the research team and to directly oversee the data and record management of the technicians, post-doctoral fellow, students, and others working under their direct supervision.

ACCESS TO RESEARCH DATA AND RECORDS
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 and the Brody School of Medicine Compliance Office acting for the University may review records and study data of projects that use human subjects to assure compliance with human subjects protection regulations. In cases involving an allegation of research misconduct, the University through the Vice Chancellor for Research, Economic Development, and Community Engagement 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 or 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 which 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.

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, three 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 three 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 animal or human subjects.

TRANSFER OF RESEARCH DATA AND RECORDS THAT SUPPORT UNIVERSITY PATENTS OR WERE FUNDED BY FEDERAL GRANTS & 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 principle 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.

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 three 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.

RESOLUTION OF DISPUTES INVOLVING RESEARCH DATA AND RECORDS
The Vice Chancellor for Research, Economic Development, and Community Engagement or his designee shall arbitrate all disputes involving research data ownership, retention, and access. Whenever possible, the Vice Chancellor or his 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 his designee shall consult with the designated Associate Deans for Research in those units.

Approved: Faculty Senate Resolution #03-04
University Chancellor
February 19, 2003