EAST CAROLINA UNIVERSITY
FACULTY MANUAL

PART VII

Faculty Research and Scholarship

PART VII – FACULTY RESEARCH AND SCHOLARSHIP

SECTION II

Scholarship/Research/Creative Activity Guidelines

CONTENTS

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

I. Funded Research

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

A. Definitions

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

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

government agencies, and by for-profit commercial entities (single owner companies, partnerships, and corporations).

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

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

B. Fundraising and Gifts

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

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

C. Contracts, Grants, and Cooperative Agreements

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

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

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

A. Statement of Ethical Principles

East Carolina University has adopted as a guiding statement of ethical principles the three principles as set forth in the report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research dated April 18, 1979, and entitled The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research include respect for persons, as implemented through the informed consent process and documents, beneficence which is applied through the analysis of known risks versus potential benefits, and justice which ensure that the burden of research is not placed on any one population and the benefits of research are open to all who might gain from their participation.

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

B. Institutional Policy

It is the policy of East Carolina University that all research activities involving humans, through direct intervention or interaction or the use of private, identifiable information about humans, and that are conducted by its faculty, staff or students must be submitted, reviewed, and approved by an appropriately established peer-review committee known as an Institutional Review Board. At ECU, there are three such committees, the Biomedical University Medical Center Institutional Review Board (UMCIRB), the Social and Behavioral Institutional Review Board (BSS IRB) and the Summer Social and Behavioral Institutional Review Board (SBSS IRB). These committees consist of scientists, non-scientists and community members. The committee must meet federally mandated membership requirements. Committee members serve four year terms, as appointed by the Vice Chancellor of Research.

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

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

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

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

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

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

C. Implementation of Policy

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

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

The IRB has the federally mandated authority to approve, modify or disapprove proposed research. It also has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to participants. The IRB is obligated to report suspension and terminations through a report to the investigator, institutional officials, and sponsoring agency, if any. Principal investigators of research studies involving humans must submit a complete protocol and address all applicable questions in e-PIRATE, upload appropriate informed consent and assent documents, and any other study related materials. Access to the electronic system, e-PIRATE, requires completion of human research protections training, registering with OHRI through e-PIRATE, and completing an Investigator Profile. A copy of all research study materials including signed informed consent and study related correspondence must be maintained by the principal investigator for at least 3 years, or longer if required by the research sponsoring agency.

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

Investigators are responsible for reporting the progress of UMCIRB-approved research to the Office for Human Research Integrity, through the use of a renewal or continuation review accessed through e-PIRATE. Federal regulations require that IRB approval be issued no less often than once per year as set forth in 45 CFR 46.109. In addition, research investigators are

responsible for reporting promptly to their department chair and to the OHRI, any unanticipated problems which involve risks to the research participants or others.

III. Animal Welfare Regulations

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

IV. Research Data and Records

A. Purpose

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

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

B. 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.)

C. 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 offered by the Office of Technology Transfer http://www.ecu.edu/cs-acad/ott/upload/Inventors-Handbook-Version-2-2.pdf. 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.

D. Custody of Research Data and Records

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

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

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

Senior members of research teams have obligations and are held responsible for discussing the responsibilities of data management and retention with other members of the research

team. The senior member of the research team must directly oversee the data and record management of the technicians, post-doctoral fellows, students, and others working under his/her direct supervision.

E. Access to Research Data and Records

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

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

F. Retention of Research Data and Records

Research data and records, including the primary experimental results, should be retained for a sufficient period to allow evaluation and repetition by others of published results emanating from those data. In general, five years from the first publication date of the research results is specified as the minimum period of retention for research published in peer-reviewed journals. For sponsored research that is not published, the minimum retention period is five years from the date of the issuance of the final report to the research sponsor, unless the sponsor specifies a longer retention period. However, if an investigation, legal action or an official inquiry concerning a research project is underway, all data and records related to the project must be retained and made accessible until all issues are resolved. In addition, the records should be kept for as long as may be required to protect any patents or other intellectual property resulting from this work. If a research project is not funded with external or designated internal funds (e.g., an internal university grant), the above retention policy shall apply to these research data and records only when the project results in a publication, its data is used to support a grant or contract application, or it involves the use of animals or human participants. If research involves the generation, use, or disclosure of protected health information (PHI), the minimum retention of those records including consent and authorization agreements must be maintained for a minimum of six years beyond the end of the project. If a participant withdraws authorization of use of PHI, the researcher must consider that request to constitute the end of the project and Day 1 of the six year retention period for that sample.

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

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

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

Exceptions:

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

H. Transfer of other Research Data and Records

In the event the responsible investigator transfers to another institution or leaves the university for any reason, the responsible investigator shall provide a true copy at university expense of his/her research data and records that have been retained less than five years in the investigator's possession per the retention paragraph above. Before his/her departure, the responsible investigator shall provide these true copies of the research data and records to his/her department chair or supervisor. These data and records shall be organized in a format to permit reasonable identification of specific experiments by individuals not involved with the

original research. These research data and records shall be used by the university only for misconduct inquiries and investigations,

I. Resolution of Disputes Involving Research Data and Records

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

V. Patents

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

The patent policy of the University of North Carolina is contained in Part 500.2 of the University of North Carolina Policy Manual. The patent policy of East Carolina University is available at http://www.ecu.edu/PRR/10/40/01. These policies address ownership of university inventions, distribution of income derived from licensing, assignment, or commercialization activities related to university inventions, and management of disputes. The patent policies also recognize limited circumstances in which publication of scholarly works may be delayed for short periods of time to allow for filing of patent applications. Premature publication or public use of an invention can constitute a statutory bar to the granting of a patent. In most cases, inventors may publish, present, and discuss their inventions freely once a patent application has been filed.

VI. Copyrights (created work)

The mission of East Carolina University to become a national model for student success, public service, and regional transformation includes using creative learning strategies and delivery methods, discovering new knowledge, and fostering innovation and entrepreneurship. Products of these activities include the 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. The university supports an open and free environment for its faculty, staff, and students to carry out their scholarly work, and encourages publication without constraint. These policies are in accord with applicable laws and pertinent university regulations. The Copyright policies of the University of North Carolina are contained in Part 500.2 and 500.2.1 of the University of North Carolina Policy Manual. The East Carolina University Copyright Regulation is available at http://www.ecu.edu/PRR/10/40/02. These policies address ownership and use of copyrightable works. (FS Resolution #12-39, March 2012 and FS Resolution #15-70, May 2015)