East Carolina University

Postdoctoral Scholar Handbook

Office of Postdoctoral Affairs

https://rede.ecu.edu/postdoctoral/

Research, Economic Development & Engagement East Carolina University Uptown 209, 209 East Fifth Street, Greenville, NC 27858 Revision August 2022

Postdoctoral Scholar Handbook Revised August 2022

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Office of Postdoctoral Affairs

The Office of Postdoctoral Affairs (OPA) at East Carolina University was established in 2008 within the graduate school to ensure successful training and work experience for postdoctoral scholars by providing a supportive working environment. In October 2013, the office was moved to Research, Economic Development and Engagement and the position of Director was established. Postdoctoral Scholars are a growing population at ECU, and we are committed to supporting the career development of these important members of our community.

Six core competencies have been defined by the National Postdoctoral Association. These serve to guide the Postdoctoral Scholar, Mentor and Institution of those skills that should be achieved for the Scholar to ultimately achieve intellectual and professional independence and success:

Discipline-specific conceptual knowledge Research skill development Communication skills Professionalism Leadership and management skills Responsible conduct of research

With these competencies as a guide, the OPA and departments of the ECU Postdoctoral Scholar Association seek to increase scholar engagement and participation in the association and in career development programs and opportunities.

Mission Statement

To advance the research and related missions of ECU through the enhancement, support, and promotion of Postdoctoral training at East Carolina University and to prepare Postdoctoral Scholars for successful careers.

Goals

- To serve as the central resource unit for Postdoctoral Scholar issues on campus
- To develop a sense of community among ECU Postdoctoral Scholars and to integrate them into the larger university and the whole Greenville community at large community
- To provide career and professional development programs and services
- To assist in the recruitment and retention of Postdoctoral Scholars at ECU

ECU Postdoctoral Scholar Policies

1. Introduction

East Carolina University (ECU) hosts Postdoctoral Scholars (Scholars) in diverse departments and centers with the goals of continuing their academic training and enriching the research environment of the Institution. Given the unique nature of their association with the University, these policies have been developed to better outline the University's and the Scholar's obligations and expectations in various contexts. The policies will be overseen by the Office of Postdoctoral Affairs (OPA), which is housed in Research, Economic Development and Engagement and is tasked with maintaining processes, procedures, handbooks and other materials related to Scholars at ECU.

2. Definition of Scholars

East Carolina University will be guided by, but not be bound by, the standards of the FASEB (Federation of American Societies for Experimental Biology) to define Scholars. This includes the following criteria:

- Prior to the start date, the appointee shall present to the Office of 2.1. Postdoctoral Affairs documentary proof, satisfactory to the University, that he/she was awarded the degree required for the position (e.g., a PhD, equivalent doctorate or terminal degree, for example, ScD, MD or MFA) or a Registrar's statement or official transcript indicating that all degree requirements have been completed. If the documentary proof of degree award is in a language other than English, then a reliable English translation, satisfactory to the University, shall be provided to the Office of Postdoctoral Affairs within three months after the start date, in which case continuation of the appointment beyond three months is contingent upon compliance with this requirement. If the required degree is in progress on the start date, documentation satisfactory to the University that the degree was awarded must be provided to the Office of Postdoctoral Affairs within three months after the start date, in which case continuation of the appointment beyond three months is contingent upon compliance with this requirement.
- **2.2.** The appointment is temporary and terminable at will, at the discretion of the University.
- **2.3.** The appointment involves substantially full-time research or scholarship.
- **2.4.** The appointment and research training are intended to be preparatory for a full-time professional career.

- **2.5.** The appointment may be part of a clinical training program, if research training under the supervision of a Mentor is a primary purpose of the appointment.
- **2.6.** The appointee works under the supervision of a Mentor in a University or similar research institution, for example, a national laboratory or the National Institute of Health ("NIH").
- 2.7 The postdoc scholar is expected to carry out their research in ECU facilities in person. Full-time remote work requests will be decided on a case-by-case basis with an approval from the Mentor and the Director of the OPA.

3. Expectations of Mentors & Scholars

- 3.1. Mentors are responsible for providing advice, guidance and assistance to their assigned Postdoctoral Scholar regarding not only their specific research or scholarship goals, but also the Scholar's overall educational experience and career development. Mentors should regularly meet with their Scholar throughout their appointment, and clearly and consistently communicate the goals, objectives and expectations of their Scholar and their assigned tasks and projects. Mentors should encourage Scholars to present their work and publish the results of their research or scholarship in a timely fashion, if applicable. They should also help Scholars acquire and enhance their knowledge and technical skills based on their current and future needs. Finally, to help provide necessary feedback, Mentors are required to provide written performance evaluation of their Scholar each year (See Section 5 below). The National Postdoctoral Association (NPA) has resources for mentoring plans which can be found at https://www.nationalpostdoc.org/page/MentoringPlans.
- **3.2.** The Office of Postdoctoral Affairs strongly recommends mentors and scholars review and complete a mentor-mentee compact within one month of the scholar's appointment. The ECU OPA and PDA have developed a tailored compact based on the AAMC template.
- **3.3.** The Mentor and the department (or center or other unit) are responsible for maintaining a departmental file for each Scholar which, at a minimum, should contain copies of the Scholar's appointment and renewal letters, Individual Development Plan, annual evaluations, and records of the amount and type of leave taken. OPA maintains the official personnel record for each Scholar at the University.
- **3.4.** Postdoctoral Scholar appointments at ECU are contingent upon the Scholar's satisfactory work performance, research (or other work) progress, the existence of availability of funding and programmatic need.

<u>All Scholars, in all disciplines, schools, colleges and centers across the</u> <u>University, must meet the following expectations at all times during</u> <u>their appointment</u>:

3.3.1. Conscientious discharge of assigned duties.

3.3.2. Adherence to ethical standards.

3.3.3. Adherence to university polices on research integrity, including compliance with Public Health Service policies on research misconduct (<u>https://ori.hhs.gov/federal-research-misconduct-policy</u>). Research misconduct includes fabrication, falsification, and plagiarism. Reports or concerns about research misconduct, including intellectual property concerns, can be made into the ECU ORIC in writing, telephonically or in person and may be made anonymously. Any individual making a report of research misconduct in good faith is protected against retaliation.

3.3.3. Compliance with good laboratory practice, regulatory standards, and related University procedures and policies.

3.3.4. Observation of established guidelines and regulatory standards for research involving biohazards, human subjects and animals.

3.3.5. Open and timely discussion with the supervising Mentor regarding research progress, distribution of reagents or materials, or any disclosure of findings or techniques privately or in publications.

3.3.6. Collegial and professional conduct toward coworkers, University employees and students.

3.3.7. Compliance with all applicable University policies and procedures, including, but not limited to, those related to maintaining eligibility to lawfully work in the United States and North Carolina, the proper conduct of research and export controls, including successful completion of mandatory face-to-face Responsible Conduct of Research (RCR) training offered by the ECU Office of Research Integrity and Compliance in year one and every three years thereafter.

3.3.8. Publication and meaningful, consistent progress toward publication of the results of his/her research or scholarship, in consultation with his/her supervising Mentor.

3.3.9. Application for extramural research funding and other financial support as appropriate and/or as directed.

3.3.10. A 3-week notification to the Mentor and OPA of intent to leave the training program before the expiration of the current contractual term of employment.

4. Appointment, Renewal and Discontinuation Process

- **4.1.** The Scholar will be provided with an official contract letter from the Director of the OPA that outlines the terms of the appointment, rate of compensation, and effective dates of the appointment. Included within the letter will be a position description.
- **4.2.** Appointments are typically for a one-year or two-year period. Five years at ECU is the maximum total period that any individual may serve as a Scholar. Once the five-year maximum period of service as a Scholar has been reached, the Scholar must either be moved into an established employee position or separated from the University. This maximum total period of service refers to total time spent at ECU as a Scholar and does not include time spent at other institutions. Exceptions to these policies require authorization by the Director of Postdoctoral Affairs.
- **4.3.** Renewals, Reappointments and Extensions The University, in its sole discretion, has the option to renew or extend any appointment, subject to the availability of funds, past performance evaluations and/or any other lawful reasons.

4.3.1. Where the maximum five-year period of service will not be reached or exceeded at the time of expiration of the current appointment, the Mentor and Scholar may request a <u>renewal</u> for another term (typically of one year). This request must be made in writing to the OPA 30 to 60 days prior to the expiration of the current term. If approved, a new contract will be issued, contingent on availability of funds.

4.3.2. Where the maximum five-year period of service will not be reached or exceeded at the time of expiration of the current appointment, and the contract will not be renewed with the current Mentor, <u>reappointment</u> as a Scholar may occur with another Mentor. The Scholar may request assistance from the department chairperson in identifying other potential opportunities within the department and/or elsewhere within the University. Such requests should be made in writing no later than 90 days prior to the expiration of the current term. The department chairperson should respond in writing within 30 calendar days after receipt of the request with a decision as to reappointment and/or identifying other potential Mentors.

4.3.3. To request an <u>extension</u> of appointment beyond the maximum total period of service of five years, the supervising Mentor must submit a written request to the Director of the OPA no later than 90 days prior to

the expiration of the current term. It is generally not in the best interests of the Scholar to extend an appointment beyond 5 years. The written request must detail the exceptional circumstances that justify the requested extension and must be co-signed by the Scholar and the department Chair (or Dean when appropriate). Such "exceptional circumstances" include cases in which a Scholar took an extended leave of absence during his/her appointment or conducted research under a grant that extends beyond the maximum five-year period. Such requests will be decided on a case-bycase basis, at the sole discretion of the University.

4.4. Discontinuation of Appointment Other Than for Cause

4.4.1. Discontinuation due to Expiration of Term A Scholar's appointment for a stated term or period expires automatically at the conclusion of the stated term or on the specified date in their appointment letter/contract. <u>The appointment itself constitutes notice of</u> <u>termination and no other notice of termination shall be provided.</u>

4.4.2. At Will Discontinuation with Notice At the discretion of the University, a Scholar may have his/her appointment terminated prior to the end of the stated term, subsequent to written notice. Such written notice from the Mentor, co-signed by the Mentor's department Chair and Dean of the College or School, and the Director of OPA must be provided to the Scholar at least 60 calendar days prior to the new termination date.

- **4.5.** Discontinuation of Appointment for Cause A Scholar may have his/her appointment immediately terminated at any time during the appointment if he/she is found by his/her supervising Mentor to have violated any of the expectations of Scholars set forth herein. Discontinuation of appointment for cause is to be preceded by written notice of intent to discontinue for cause, which must be co-signed by the Mentor's department Chair, Dean or designee and Director of OPA.
- **4.6.** Responsibilities at End of Appointment Regardless of whether a Scholar's appointment ends due to resignation, discontinuation, dismissal, or otherwise, a Scholar has certain responsibilities to meet at the end of the appointment.

4.6.1. The Scholar should work with his/her Mentor to submit research results, if any, for publication by the end of appointment, if possible. The Scholar must leave all original notes, computerized files, equipment, documents and any other tangible materials in his/her possession with his/her Mentor prior to departure. These materials and information are property of the University, and the University retains the right to own,

disclose and use such materials and information at any time and for any purpose during and after the appointment.

4.6.2. The Scholar may copy notes, computerized files and other research materials that he/she helped generate during the appointment only with prior, written permission to do so from his/her Mentor and only if such reproduction is permitted under the terms of any applicable grant agreements or other contracts. Moreover, future use of any such material and information by the Scholar is limited by any conditions set forth by his/her Mentor and the terms of any applicable grant agreements or other contracts. Any confidential information obtained by the Scholar during their appointment must remain strictly confidential and may be disclosed only in accordance with federal or state law, University policy and the terms of any applicable grant agreements.

4.6.3. At the end of the appointment all Scholars are invited to participate in an exit survey. Scholars are also encouraged to share with OPA any feedback that they may have about their experiences at the University and any ideas for improving the Postdoctoral Scholar program.

5. <u>Annual Performance Evaluations and IDP Review</u>

- 5.1. Feedback, guidance and constructive criticism are important for a Scholars personal and professional growth. Therefore, at the beginning of appointment, each Scholar will prepare an Individual Development Plan (IDP) that identifies his or her professional development needs and career objectives. IDPs also serve as a communication tool between the Scholar and his/her Mentor. The IDP can be created at <u>myidp.sciencecareers.org</u>.
- 5.2. The Scholar's supervising Mentor must complete an annual written evaluation of the Scholar's performance. The evaluation criteria will be based upon duties and responsibilities stated in the Scholar's contract letter and position description. The completed evaluation form must be signed by the supervising Mentor and the Scholar and forwarded to the Director of OPA. The Scholar's signature will acknowledge receipt of the evaluation, not necessarily concurrence. The evaluation process should be simple and must include the opportunity for the Scholar to respond in writing, and this response shall be appended to the evaluation. Multiple evaluation resources are available on the OPA website.
- 5.3. Scholars are encouraged to do self-assessments following the National Postdoctoral Association (NPA) Core Competencies and checklist, which can be found at https://www.nationalpostdoc.org/general/custom.asp?page=CoreCompetencies. One of the most important uses of the Core Competencies is to provide a framework for constructive evaluation and feedback. The diversity of competencies and skills outlined in this document can be

evaluated using a number of mechanisms including informal feedback on particular skills, formal job evaluations, an Individual Development Plan (IDP) and other training program assessments. It is not the intent of this document to outline or list evaluation methods. Rather, the document should be used to help the Scholar proactively create a balanced portfolio of structured oversight and self-assessment through input from advisors, mentors, peers and colleagues. The NPA Core Competencies enforce the notion that the successful transition to intellectual and professional independence depends on the individual's responsibility to embrace selfassessment and to apply it to all the Core Competencies. There is also an annual self-assessment questionnaire found in the Appendix of this handbook.

6. <u>Compensation</u>

The ECU OPA follows the current NIH National Research Service Award (NRSA) training grants and fellowships guidelines. Scholars must be hired at or above the current salary minimum for the number of years of experience. In accordance with the federal Fair Labor Standards Act, scholars will not be entitled to overtime pay. Salaries must be approved by the OPA and must not exceed 10% of the current NRSA guidelines.

Annual salary increases for postdoctoral scholars are based on the NRSA guidelines for additional years of experience and required unless otherwise proscribed by state, university system, or campus directives. However, after consultation with the OPA Director, reappointment salaries may vary based on performance reviews, funding availability, and/or merit and equity considerations.

7. <u>Benefits</u>

- 7.1. Leave is granted based on appointment year (as opposed to calendar year) starting with the Postdoc's appointment date. Full-time (1.0 FTE) Scholars shall receive: (a) twelve (12) days of paid vacation leave per appointment year (in addition to recognized University holidays) and (b) twelve (12) days of paid sick leave per appointment year. In addition, scholars are eligible for eight hours of paid leave per year to be used as a single day for personal use (described in 7.5 below). Vacation leave and sick leave will be awarded annually at the time of appointment and reappointment. Vacation and sick leave do not accrue and cannot be carried over to the next appointment year. In other words, a Postdoc's compensated leave expires one year from the date of appointment. Subject to the same maximums, leave is prorated for part-time Scholars who work half-time or more (from 0.50 to 0.99 FTE). It is the responsibility of the department to maintain leave records for each Scholar. Unused vacation and sick leave will not be paid out when the Scholar's appointment ends.
- **7.2.** A Scholar is eligible for 30 paid workdays for parental leave per year consecutive from the day of the qualifying event to care for a new

biological or adopted child. The start date of the first leave sets the clock for the 12-month period for leave.

7.2.1. Requests for parental leave must be provided in writing to the supervising Mentor and department Chair at least ninety (90) days before the anticipated start of parental leave or as soon as possible under unforeseen circumstances. The Scholar must provide appropriate supporting medical documentation to University Human Resources for its review and approval.

7.2.2. Scholars may be eligible for an additional 30 consecutive workdays of unpaid job-protected parental leave if they meet the eligibility requirements described in section 7.2. University Human Resources should be consulted for any additional requirements. Scholars must maintain health benefits at their own cost during unpaid parental leave.

7.2.3. Requests for unpaid leave by international Scholars on a temporary visa will be reviewed by the University Office of Global Affairs and may not be approved if it is determined to constitute a violation of their visa status. International Scholars who request unpaid leave must do so BEFORE the start of the leave occurrence.

7.2.4. A Scholar on an active postdoctoral assignment of at least .75 FTE is eligible for health insurance benefits.

- **7.3.** A Scholar is not eligible for participation in ECU retirement benefits, or any other benefits, unless expressly provided for hereunder.
- **7.4.** The university accommodates the religious observances and practices of students and employees except where such accommodation causes undue hardship for the university. The extent of the university's obligation is determined initially by considering statutory requirements; and any obligation of accommodation beyond that shall be determined with consideration of business necessity, financial costs and expenses, and resulting personnel and/or academic problems.
- 7.5. A Scholar is eligible for eight hours of paid leave per year to be used as a single day for personal use, which includes but is not limited to: days of cultural or religious significance, community service, and observation of Juneteenth and PRIDE celebrations. If this leave is not used, it expires at the end of each year of appointment and is not paid out.

8. <u>Grievances</u>

A Scholar may initiate a written grievance to challenge and obtain review of discontinuation, non-renewal of appointment, or other material matters of concern related

to his/her appointment, if, and only if, the Scholar alleges that such action was in violation of law or applicable University policy (which may include this policy and/or those policies that prohibit illegal discrimination and retaliation). A Scholar may use the following procedures to initiate and pursue a grievance:

- **8.1.** No later than 14 calendar days after receipt of notice of the facts and circumstances giving rise to a grievance, the Scholar must initiate the grievance process by making a reasonable effort to resolve the matter through a personal meeting or telephone call with the person against whom the grievance is directed (the "Respondent").
- **8.2.** However, a Scholar is not required to meet with the Respondent if the Scholar alleges that Respondent has engaged in illegal harassment against the Scholar (in such circumstances the Scholar shall instead bring the matter directly to the attention of the Respondent's immediate supervisor and attempt to resolve the matter through a meeting as described in section 8.1). *NOTE: Where the Scholar alleges he/she has been unlawfully harassed, discriminated against and/or retaliated against by any University employee, student, visitor, or another Scholar, the Scholar should also contact the University Office for Equity and Diversity (OED) and the Director of OPA to receive guidance on how to proceed with this grievance process, if at all, in light of the allegations. Under such circumstances, the University may determine that this grievance process should be put on hold or discontinued, pending the outcome of an investigation by OED.*
- 8.3. This section describes follow-up procedures for matters that are NOT on hold pending the outcome of an OED investigation. If the matter is not resolved to the Scholar's satisfaction pursuant to the procedure described in section 8.1, by meeting with the Respondent, or that person's immediate supervisor, as the case may be, the Scholar may in writing formally request resolution of his/her grievance. This written request shall be made to the immediate supervisor of the Respondent, unless the immediate supervisor conducted the meeting described in section 8.1 or the immediate supervisor is named as a Respondent in the Scholar's grievance, in which case the grievance shall be directed to another appropriate administrator above the immediate supervisor of the Respondent. The request must be delivered to the Respondent's supervisor, or another appropriate administrator above the Respondent's immediate supervisor, as the case may be, no fewer than 14 calendar days after the conclusion of the meeting described in section 8.1. The request must include a written statement describing the matter of concern, the supporting facts, and the results of prior discussions. The request must address three critical questions: (a) What is the grievable offense? (b) Who committed the grievable offense? (c) What is the desired resolution? In addition, the grievance must specify the law or University policy (which

may include this policy and/or those policies that prohibit illegal discrimination and retaliation) allegedly violated. Any request failing to meet the requirements of this section may be dismissed, pending review by the Director of the OPA. The Respondent's supervisor/other appropriate administrator shall resolve the matter as promptly as reasonably possible by providing the Scholar a written decision and outlining the reasons for the decision, within 14 calendar days from receipt of the written request and receipt of any other information the Mentor's immediate supervisor/other appropriate administrator reasonably determines is necessary for the rendering of an informed decision. This decision shall be final unless the Scholar timely initiates the formal request described in the next section.

- 8.4. If still unresolved to the Scholar's satisfaction, the Scholar may formally request resolution by the Dean of the School or College in which the Respondent is appointed or by another appropriate administrator above the Respondent's immediate supervisor (if the Dean rendered the decision in section 8.3 or the Dean is named as a Respondent in the Scholar's grievance). The written request must be delivered to the Dean or other appropriate administrator, as the case may be, no fewer than 14 calendar days after the Scholar's receipt of the decision described in section 8.3, include a copy of that decision and all information described in 8.3 above. The Scholar's written request must also include the reasons why the decision rendered pursuant to section 8.3 was flawed. The scholar's written request must also include the reasons why the decisions rendered pursuant to Section 8.3 was flawed. Any request failing to meet all the requirements of this section may be dismissed, pending review by the Director of the OPA. The Dean or other appropriate administrator shall resolve the matter as promptly as reasonably possible, providing a written response outlining the reasons for the decision within 14 calendar days from receipt of the written request and receipt of any other information the Dean/administrator reasonably determines is necessary for the rendering of an informed decision. This decision shall be final unless the Scholar timely initiates an appeal as provided in the next section.
- 8.5. To the extent that the Dean or other appropriate administrator's decision was unfavorable to the Scholar, no fewer than 14 calendar days after the Scholar's receipt of the decision from the Dean or other appropriate administrator he/she may appeal in writing to the Director of OPA or other appropriate administrator (if the Director rendered the decision in section 8.4 or the Director is named as a Respondent). The written appeal must include all information as described in 8.3 above, copies of all previous written decisions and the reasons why the decision by the Dean or other appropriate administrator was flawed. Any appeal failing to meet all the requirements of this section may be dismissed, pending review by the Director of the OPA. The Director shall render a final decision based upon

the written information provided as promptly as possible, providing a written response outlining the reasons for the final decision within 14 calendar days from receipt of the written appeal and receipt of any other information the Director/administrator reasonably determines is necessary for the rendering of an informed decision.

- **8.6.** Upon timely initiation of a grievance and a final outcome that upholds a discontinuation of appointment, the Scholar's discontinuation shall be effective as of the date of the final decision in the grievance procedure. If a Scholar timely initiates a grievance and the final outcome is not to uphold the discontinuation of appointment, then, if more than 60 days remain on the appointment, an at will discontinuation may be pursued, requiring 60 calendar days' notice following the date of the final decision in the grievance procedure.
- 8.7. Notwithstanding the foregoing, as provided by University policy prohibiting illegal discrimination and retaliation, any Scholar may contact the University Office for Equity and Diversity (OED) at any time with concerns that he or she has been unlawfully harassed, discriminated against and/or retaliated against, by a University employee, student, visitor, or another Scholar based on one of the University's protected classes. For more information see, OED's website at http://www.ecu.edu/oed or contact OED directly by telephone at (252) 328-6804 or by email at OED@ecu.edu.

RESEARCH SERVICES

CONFLICTS OF INTEREST AND COMMITMENT

ECU's PRR Regulation on Conflicts of Interest and Commitment," as stated in Part VIII of the Faculty Manual requires all Professional Staff to complete a Conflict of Interest form annually, whether or not they have any of the relationships that may be deemed to compete with their University responsibilities. A statement regarding conflicts of interest is located on the Research, Economic Development and Engagement website: <u>https://ecu.myresearchonline.org/air</u>

An electronic campus Conflict of Interest and Commitment disclosure site with links to additional conflict of interest material is available online at http://www.ecu.edu/cs-acad/fsonline/customcf/facultymanual/appendixi/appendixi.htm

If you have questions about this policy, contact: Ms. Deb Elek, Director for the Office of Research Integrity & Compliance. Telephone number: 252-328-9473.

RESEARCH CENTERS AND INSTITUTES

In addition to academic departments, ECU contains a number of Centers and Institutes in which research is fundamental to their mission. A listing of these can be found at: <u>https://rede.ecu.edu/research-centers-institutes/</u>. This site contains links to each Center and Institute.

HUMAN SUBJECTS IN RESEARCH

All behavioral or biomedical research involving human subjects conducted at or sponsored by ECU must be reviewed an Institutional Review Board (IRB) prior to the involvement of those subjects. The institutional human subjects in research policy can be found at: http://www.ecu.edu/cs-acad/fsonline/customcf/facultymanual/part7/74.htm.

The primary function of the University and Medical Center Institutional Review Board (UMCIRB) at ECU is to protect the rights and welfare of human subjects engaged in research at East Carolina University, The Brody School of Medicine, Vidant Medical Center and its affiliates, and in research conducted elsewhere by faculty, students, staff or other representatives of ECU in connection with their responsibilities. This mission is accomplished by an institutional commitment to education and establishment of a collaborative relationship with the researchers and key support staff. The UMCIRB URL is: <u>http://www.ecu.edu/ORIC/IRB/</u>.

Researchers are encouraged to contact the relevant IRB to obtain the necessary guidelines, forms, and schedule of meeting dates.

ANIMAL SUBJECTS IN RESEARCH

Every investigator must understand the laws and regulations that govern the use of animals for research and to incorporate them into their research efforts. Although there are many federal, state and local regulations governing the use of animals, there are two main sets of regulations with which the investigator should be familiar. These are the "Animal Welfare Act" enforced by the United States Department of Agriculture (USDA) and the Public Health Service (PHS) "Policy on Humane Care and Use of Laboratory Animals" administered by the Department of Laboratory Animal Welfare. Many of the USDA regulations are similar to those of the PHS policy.

Both of these policies require each research institution to establish an Institutional Animal Care and Use Committee (IACUC) with defined responsibilities. These include the review of all proposed activities related to the care and use of animals, semi-annual review of the institution's program for animal care, and semi-annual review of all animal facilities and animal research areas.

Federal policy directs IACUC to evaluate research proposals by investigators to ensure that the number of experimental animals is appropriate, non-animal alternatives are used if possible, any pain or distress is minimized, use of animals has been justified, activities do not unnecessarily duplicate previous efforts, personnel are appropriately qualified, and animal activities are in accord with the USDA regulations and PHS policy. ECU is an elective member of the Association for the Assessment and Accreditation of Laboratory Animal Care International (AAALAC).

Researchers should direct questions about the use of vertebrate animals to any of those listed at the end of this section.

ECU is committed to the human and ethical treatment of animal subjects in research. The Institutional Animal Care and Use Committee (IACUC) fosters compliance through facilitating the efforts employed by the institution's scientists and instructors in the utilization of the animals in research, education and other scholarly pursuits.

For more information about the IACUC, please e-mail us (<u>iacuc@ecu.edu</u>). Additionally, feel free to contact the following individuals or departments for assistance.

IACUC Chair Dr. Susan McRae <u>mcraes@ecu.edu</u> 252-328-6515 University Veterinarian Dr. Dorcas O'Rourke <u>orourked@ecu.edu</u> 252-744-2420

IACUC Director Dr. Gaelle Deshayes .252-744-2436

INTELLECTUAL PROPERTY

East Carolina University is dedicated to the pursuit of knowledge in the form of research and other scholarly activities in an environment that embraces collaboration and publication of scholarly results. Inventions, discoveries and other intellectual assets may also result from the conduct of these activities. These assets may contribute to development of new products and services that could benefit from intellectual property protection in the form of patents and copyrights. The Board of Governors of the University of North Carolina has determined that patenting and commercialization of these assets is consistent with the mission of the University. The Patent and Copyright policies of East Carolina University provide valuable direction on such matters as how and when to disclose new inventions to the University, determining ownership of intellectual assets, defining responsibility for commercialization activities, and the process for distribution of any income earned as a result of these activities. Compliance with these policies is a condition of employment for University employees, enrollment of University students, and access to University facilities by visitors and volunteers.

The <u>Office of Licensing and Commercialization</u> is responsible for all issues related to University inventions, such as performing market and intellectual property assessments, securing intellectual property protections, identifying industry and commercialization partners, and negotiating license agreements. This office also facilitates engagement of collaboration partners in the review and use of ECU intellectual property through Material Transfer Agreements and Confidential Disclosure Agreements.

Invention Disclosure

Disclosure of inventions to ECU is important for a variety of reasons. First, ECU has a duty to review and respond to inventions that are developed with institutional resources. Second, ECU is required to submit periodic reports to the federal government about the status of federally funded inventions. Third, Licensing and Commercialization can provide valuable guidance in the evaluation, protection and development of inventions. To obtain maximum intellectual property protection, a disclosure should be made prior to submitting data for publication or presenting to a group of non-ECU personnel.

Invention Ownership

Consistent with the intellectual property policies of ECU and the University of North Carolina, ECU generally owns the intellectual property rights generated as a result of use of ECU facilities, equipment or funds. This is particularly true for patentable inventions generated by faculty, staff, postdoctorates, students or guests of the university. Ownership of copyright rights depends on whether the work created is a scholarly work, a directed work or one that utilizes exceptional use of university resources. Further guidance about ownership of intellectual property rights is contained in the ECU Patent Policy POL10.40.01.

Discussing Your Invention with Others

Public disclosure of an invention in either written or oral form may create challenges to obtaining patent protection for new inventions. Examples of public disclosures include published articles, abstracts, posters, seminar descriptions, grant proposals, and theses and dissertations. While the United States allows a one-year grace period to file a patent application following public disclosure of an invention, most other countries do not make

such an allowance. To maximize protection of University inventions, the <u>Office of Licensing</u> and <u>Commercialization</u> should be notified immediately if a public disclosure of an invention is anticipated.

Confidentiality and Material Transfer Agreements

Unpublished information and research data generated by ECU personnel may benefit from terms of confidentiality found in a Confidential Disclosure Agreement (CDA) or Non-Disclosure Agreement (NDA) prior to disclosure to collaborators from other organizations or potential industry partners. CDAs and NDAs recognize the proprietary nature of unpublished information and restrict the manner in which the information can be used by the receiving party. Similar protection is available in the form of a Material Transfer Agreement (MTA) for tangible research materials such as cell lines, antibodies, vectors, animal models, computer chip design, and software. The Office of Licensing and Commercialization can assist with drafting, review and negotiation ofCDAs, NDAs and MTAs.

For more information about the disclosure, assessment, and the commercialization process for University inventions, contact the Office of Licensing and Commercialization at (252) 328-9549 or visit <u>https://rede.ecu.edu/innovation/</u>. The office is also a valuable resource for advice when sharing research information or materials is anticipated with non-ECU collaborators or potential industry partners.

Intellectual Property Policies and Inventor Resources

- ECU Patent Policy: <u>https://www.ecu.edu/prr/10/40/01</u>
- ECU Copyright Policy: https://www.ecu.edu/PRR/10/40/02/
- ECU Inventor's Handbook: <u>https://rede.ecu.edu/innovation/inventors-handbook/</u>
- ECU Office of Licensing & Commercialization: <u>https://rede.ecu.edu/innovation/</u>

OFFICE OF CLINICAL TRIALS

The main focus of the Office of Clinical Trials (OCT) at ECU is to provide support for clinical research. By working closely with investigators, we strive to facilitate the approval process and to improve the overall quality of clinical research. Our goals include ensuring compliance with federal, state and institutional regulations, policies and procedures in order to protect the interests of patients and of the university.

The OCT provides certified, experienced study coordinators to assist principal investigators with all clinical requirements related to their studies. The OCT website is: http://www.ecu.edu/clinicaltrials/.

OFFICE OF RESEARCH ADMINISTRATION

The Office of Research Administration (ORA) assists faculty, staff, and students in obtaining and managing external grants and contracts to support research, instruction, and service

activities. ORA coordinates with the Office of Research Development in identifying funding opportunities and preparing and submitting proposals on behalf of the University, with a focus on assuring that proposals comply with University and sponsor requirements. Additionally, ORA negotiates and accepts awards from sponsors, issues sub-awards under funded projects, and oversees other award actions such as incremental funding actions, award modifications, and no-cost extensions. ORA's eTRACS electronic proposal routing and approval system tracks proposal submissions and awards, providing valuable information to faculty for annual evaluation purposes and to ECU and UNC administration for assessment and strategic planning purposes.

Revision History

Revision date: August 2022