NOVA SOUTHEASTERN UNIVERSITY

DIVISION OF RESPONSIBILITIES FOR RESEARCH AND SPONSORED PROGRAMS

Vice President of Research & Technology Transfer:

The responsibilities of the Vice President of Research & Technology Transfer are summarized below:

1. Administrative oversight to the Office of Sponsored Programs and is responsible to the University and to the funding agencies for the pre and post award functions and regulations associated with research contracts, grants, sponsored programs.
2. Administrative oversight to the Office of Clinical Research and is responsible to the University and to the funding agencies for the functions and regulations associated with clinical research contracts and grants.
3. Administrative oversight to the Office of Technology Transfer and is responsible to the University and to the federal government for the functions and regulations associated with technology transfer.
4. Administrative oversight for research-premised business development, research-premised economic development and the Collaborative Research Building and Research Park.
5. Administrative oversight to the Grant Lab and is responsible for functions and regulations associated with proposal development and grant writing.
6. Assist in the development of Research Oversight Committee(s) that currently do not exist within the University and provide administrative support to the Research Oversight Committees that currently exist within the University to ensure compliance with various federal laws and regulations relating to research activities including but not limited to:
   a. Animal Welfare Committee: The Animal Welfare Committee supervises all vertebral animal use at NSU as required by Federal regulations to ensure all practices are humane and in compliance with the law.
   b. Biosafety Committee: The Biosafety Committee reviews and approves the use of recombinant DNA and other biohazardous agents in research activities.
   c. Radiation Safety Committee: The Radiation Safety Committee reviews and approves the use of radiation generating equipment (therapeutic, diagnostic, and analytic), radioactive materials, and lasers for clinical, research and educational purposes.
   d. The Human Subject Research Committee of the Radiation Safety Committee reviews and approves protocols with radiation use involving human subjects as a consultant for the IRB, and the Radioactive Drug Research Committee reviews and approves use of radioactive drugs by human subjects enrolled in an approved IRB protocol.
8. Development of a Conflict of Interest in Research and Educational Activities Policy.

9. Serve as the Research Integrity Officer (RIO) who will have primary responsibility for implementation of the institution’s policy and procedures on research misconduct. (Please see the NSU Faculty Policy Manual, Research Misconduct)

10. Development of a Research Integrity Policy. Such responsibilities include, but are not limited to:

   a. Establish, communicate and promote policies and procedures consistent with federal, state and sponsor regulations;
   b. Provide university-wide research-premised budget guidance to comply with regulations, promote uniformity, streamline processes, create incentives and continuously improve;
   c. Provide support and guidance to college business offices, Deans and faculty for the effective administration and financial management of grants, contracts, and sponsored projects;
   d. Development of a Research Advisory Committee [RAC]. The RAC shall work with the General Counsel’s Office, the Research Compliance Committee [RCC] to provide leadership and direction for the University’s research mission and serves to interface with the Research Compliance Committee to address recommendations from the Research Compliance Committee related to implementation and operation of the University’s Research Compliance Plan. The Research Advisory Committee shall include but not limited to the University’s above referenced Research Oversight Committees; V.P. for Finance; Office of Sponsored Programs; and Technology Transfer.

**Office of Sponsored Programs:**

The responsibilities of the Executive Director of Sponsored Programs are as follows:

   a. Establish and communicate policies and procedures necessary to ensure compliance with applicable contract and grant terms, Federal and State regulations and NSU policies and procedures;
   b. Work with the V.P. of Finance to establish effective cash management systems to ensure cash flow and the corresponding collection and deposits to respective contract and grant accounts;
   c. Negotiate the indirect cost rate for individual awards;
Such responsibilities include, but are not limited to:

**Pre-award Functions:**

1. Establish and communicate policies and procedures consistent with federal, state and sponsor regulations and requirements;
2. Identification and dissemination of funding source information;
3. Liaison with funding sources;
4. Assistance with identification and conceptualization of projects/programs;
5. Assistance with preparation of pre-proposal or proposal;
6. Assist with budget preparation and ensure budgets and records are retained and submitted to sponsoring agencies are in compliance with all applicable university policies and procedures, sponsor regulations and requirements, and Cost Accounting Standards as established and maintained by Grant Accounting;
7. Review and submission of proposals;
8. Completion of assurances/certifications; Resolution of compliance issues;
9. Coordination of contract/subcontract review by university legal counsel; and
10. Negotiation and acceptance of award. Completion of various reviews, required and ad hoc reports, corrective actions, etc. related to pre-award activities.
11. Review and validate appropriate support documentation for cost sharing.
12. Provide an effective research contract and grant management system to monitor compliance with reporting requirements as established by Federal and State law, agency regulations, NSU policies and procedures for sponsored projects awarded to NSU.

**Post-award functions:**

1. Conduct pre-audit reviews of all charges to sponsored awards to ensure that expenditures and subsequent adjustments to expenditures are reasonable, allowable, allocable, timely and non-personal and applied consistently in like circumstances and determine the propriety and reasonableness of costs;
2. Coordinate formal audits or interim reviews of contracts and grants by sponsoring agencies;
3. Exercise budgetary control of contracts and grants funds;
4. Review and validate subcontractor costs for reasonableness and compliance with prior approval and cost sharing requirements before processing invoices for payment.
5. Ensure compliance with cost sharing commitments on sponsored projects;
6. Review and validate monthly reviews of charges to sponsored awards to ensure that all charges were pre-audited. Review and validate that no unallowable or unrelated costs were charged to the project in error;
7. Process prior approval requests when sponsor has delegated the authority to submit requests to other University offices or the sponsor when necessary;
8. Maintain an effective, auditable effort reporting system including monitor and provide follow up regarding the committed level of effort on sponsored projects, grants and research contracts and monitor all payroll reallocation transactions;
9. Monitor and review the compliance by the College/PI with appropriate completion, certification, and timely return of effort reports. Permanent changes to the labor distribution are made by the College prior to the start of the certification period and changes (5% variance) resulting from certification are made in the payroll system within 30 days of the close of the certification period.
10. Coordinate formal audits or interim reviews of contracts and grants by sponsoring agencies;
11. Complete and execute all certifications required by the Office of Sponsored Programs;
12. Complete various reviews, required and ad hoc reports, corrective actions, etc. related to post-award activities;
13. Monitor departmental accounts for re-budgeting, overdrafts and budget compliance.
14. Collect, receive and archive reports and invoices prepared by the Office of V.P. for Finance.
15. Obtain and retain all financial reports and invoices prepared by the Office of Vice President for Finance based upon appropriate Cost Accounting Standards and written justifications. Provide these justifications when requested to internal and external auditors.

**Office of Clinical Research:**

The Administrative Director of the Office of Clinical Research is responsible to the University and to the funding agencies for the regulatory, budget development, and administration of clinical research contracts and grants.

**Assistant Vice President of Research and Technology Transfer:**

It is the responsibility of the Assistant V.P. for Research and Technology Transfer, acting as an attorney in a legal capacity, to prepare and/or perform the legal review of the research-premised agreements, grant agreements, sponsored program agreements and other legal documents related to sponsored programs, clinical research or technology transfer. In addition, the Assistant V.P. will work with Sponsored Programs, Office of Clinical Research and Technology Transfer to provide the PI/Dean/College with written guidance and direction and her legal opinion where deemed necessary on the regulatory and contractual requirements associated with their research. **The Assistant V.P. for Research and Technology Transfer will provide the “Regulatory Checklist” for each Federal agency tailored for the specific research and/or sponsored program.** The Assistant V.P. for Research and Technology Transfer will provide the V.P. for Research and Technology Transfer and the Office of the Presidents with her legal opinion and approval and/or disapproval of the said research-premised and technology transfer agreements.
The Assistant V.P. for Research and Technology Transfer will consult with general counsel pertaining to any state or federal regulatory issues at her discretion.

In addition, all research related contracts, grants, sponsored projects or other written instruments that meet the following criteria must be approved as follows:

- a. have a monetary obligation in excess of $15,000
- b. are for a term of more than one (s) year, or
- c. contain provisions relating to liability, default, indemnification or insurance

Must be approved by NSU’s Assistant Vice President for Research and Technology Transfer and signed by the Chancellor, or President, and the Vice President of Research and Technology Transfer or the Executive Director of Sponsored Programs.

Research premised insurance requirements are handled by the Risk Management Office.

**Vice President of Finance:**

It is the responsibility of the Vice President of Finance to exercise administrative oversight to the Controller, Associate Controller and Associate Director of Grants Accounting and is responsible to the University for the following the following responsibilities:

- a. Provide an effective research contract and grant management system to monitor compliance with fiscal and reporting requirements as established by Federal and State law, agency regulations, NSU policies and procedures for sponsored projects awarded to NSU;
- b. Monitor departmental accounts for re-budgeting, overdrafts, and compliance with the cost accounting standards;
- c. Conduct periodic review of charges to sponsored awards to validate that no unallowable or unrelated costs were charged in error; and
- d. Monitor departmental accounts for rebudgeting, overdrafts and budget compliance;
- e. Obtain and retain appropriate Cost Accounting Standards and written justification. Provided these justifications, when requested, to internal and external auditors;
- f. Maintain the University’s Cost Accounting Standards Disclosure Statement, if applicable.
- g. Manage and allocate indirect cost funds collected by NSU in accordance with NSU policies and procedures;
- h. Prepare the Schedule of Expenditures of Federal Awards and State Financial Assistance and Data Collection Form as required for compliance with A-133 and submit to the Vice President of Finance for distribution;
- i. Prepare monthly expenditure report for PDs/PIs and follow up with PDs/PIs regarding their expenditure rates;
- j. Review and approval by accountant of all invoices on grants and contracts not completed by accounting.
- k. Make timely deposits of contract and grant receipts from sponsors and follow up with sponsors on delinquent payments;
l. Complete drawdown of funds in a timely manner;
m. Submit final financial reports, equipment inventories and intangible asset
disclosure statements to the Vice President of Finance for distribution to the
funding agencies.
n. Complete timely fiscal close-out of grants and contracts;
p. Complete various reviews, required and ad hoc reports, corrective actions, etc.
related to Accounting Activities.
q. Send all financial reports and invoices prepared by the Office of V.P. for Finance
to the Office of Sponsored Programs.

**Director of Corporate Compliance Responsibilities:**

It is the responsibility of the Director of Corporate Compliance to exercise administrative
oversight to the Associate Compliance Officer for Research and is responsible to the University
for the following the following responsibilities:

a. Ensure that a periodic risk assessment of research and sponsored program
activities is conducted;
b. Review relevant risk areas and is consistent with applicable laws and regulations,
as well as institutional research compliance activities;
c. Serve as a resource for each University research oversight committee, board, or office in their development, implementation and coordination of policies, training and monitoring programs;
d. Develop training programs pertaining to federal agency requirements and
applicable federal and state requirements and monitoring activity related to
research compliance activities;
e. Conduct internal audits and direct and assist with external audits of research
compliance activities;
f. Review and respond to internal or external reports of alleged research non-
compliance;
g. Coordinate investigation of matters related to non-compliance through the
applicable research oversight committee, board, or office;
h. Coordinate with General Counsel the self-reporting of any identified violations of
federal requirements; and
i. Maintain the vitality of the research compliance program through on-site visits,
bulletins, and notification of risk areas.
The Research Compliance Plan provides guidance to the NSU research
community and support to the University research oversight committees, boards
and offices. The Research Compliance Plan will integrate the guidance of all
University research oversight committees, boards, and offices to ensure that the
University’s research activities meet the ethical standards of the University. The
Research Compliance Plan will provide guidance to the University research
community regarding responsible conduct of research; and
k. Development and implementation of a Research Compliance Committee to assist
in developing and implementing, and overseeing the Research Compliance Plan.
The Research Compliance Committee shall be composed of the Associate Compliance Officer for Research and including but not limited to a representative from the University’s Research Oversight Committees, Boards, and Offices; Grants and Contracts, General Counsel’s office, and a faculty member who is active in research from each college.

**College Responsibilities:**

It is the responsibility of the Dean of each College/Schools or his/her designee to exercise and be responsible for administrative oversight in writing with respect to certain compliance and pre-audit functions as follows:

- a. Provide necessary training within the college for each employee;
- b. Ensure consistency in budgeting of direct costs vs. facilities and administrative (F&A) costs (pre-award phase);
- c. Ensure consistency in charging of direct vs. F&A costs (pre-audit function);
- d. Ensure prior approvals for expenditures and activities are obtained when required. Requests for prior approval should contain adequate justification to determine the impact of the request on the technical aspects of the project as well as its reasonableness in terms of costs;
- e. Prior approval requirements for each sponsored project can be determined by reviewing the following documents: "Regulatory Checklist" for each Federal agency provided by the Assistant Vice President of Research & Technology Transfer tailored for the specific research, grants and/or sponsored program. Project Digest (if a new award meeting was requested by the college).
- f. Award document and any regulations cited therein
- g. Establish internal procedures to ensure timely processing of personnel actions (e.g. with 2 weeks), forms required to document a change in time and effort which affects sponsored awards and payroll adjustments which affect sponsored awards;
- h. Ensure the conscientious completion, certification, and timely return of effort reports. Permanent changes to the labor distribution are made prior to the start of the certification period and changes (5% variance) resulting from certification are made in the payroll system within 30 days of the close of the certification period;
- i. Prevent budget overdrafts;
- j. Ensure all adjustments to expenditures are performed timely;
- k. Review subcontractor costs for reasonableness and compliance with prior approval and cost sharing requirements before processing invoices for payment;
- l. Perform monthly reviews of charges to sponsored awards to ensure that all charges were accurate and appropriate. Determine that no unallowable or unrelated costs were charged to the project in error;
- m. Provide timely account close-out notices and timely processing of close-out adjustments as per the project digest;
- n. Ensure all technical reports are completed and submitted on a timely basis; and
- o. Obtain and retain appropriate support documentation for financial transactions within one (1) year of close of contract, grant or sponsored project
Responsibilities of the Principal Investigator (PI):

PI’s on approved sponsored programs will comply with the following specific responsibilities and activities:

1) The proposed project will be carried out within the framework of an established department or division of the university or through the cooperation of several departments or divisions. Student involvement in sponsored projects will be under the direction of the PI.

2) A proposal for sponsored programs will have the administrative approval of the appropriate department head(s), dean, and or director indicating the proposal has been examined and meets the following qualifications:
   - the proposed sponsored project has academic merit;
   - the proposed sponsored project is consistent with the overall academic interests of the department(s);
   - the department has adequate facilities which have been approved and will be available for the successful conduct of the proposed project; and there is reasonable assurance the technical or student assistance specified in the proposal will be available and the time and effort commitment of the PI is acceptable.

3) The project proposal will have the approval of the appropriate dean(s), director(s), or their designees.

4) The budget for the proposed program will be adequate for the work proposed, including allowances for contingencies and salary increases. Any university contribution, in the form of either direct or indirect expenses, will be specifically identified as to source at the time the proposal is submitted and must be approved by the applicable Dean of the academic unit.

5) The proposed award will comply fully with university administrative regulations and academic policies, such as those regarding employment and employee relations, safety, safeguards to human subjects in research, fiscal and purchasing procedures, and animal care as certified by the Office of Sponsored Programs or the Office of Clinical Research accordingly.

6) The award will not interfere with the normal prerogative to publish the results of properly conducted investigations.

7) The acceptance of funds to support a project will be construed as evidence the PI has agreed to comply with all policies or requirements of the supporting agency which are pertinent to the project, including the timely preparation and submission of all necessary reports and publications.

8) The PI will not contract for or commit the utilization of university facilities, resources, or personnel without going through the prescribed university channels as detailed above.

9) The PI who accepts funds from a sponsor in support of research will comply with the university’s policy on “Conflict of Interest.”

10) The PI is responsible for the scientific, technical, or programmatic aspects of the grant and for day-to-day management of the project or program.
11) The PI is part of the university team responsible for ensuring compliance with the financial and administrative aspects of the award. This individual works closely with the Office of Sponsored Programs, (OSP) and the Office of Contract and Grant Accounting (CGA), including Payroll, to create and maintain necessary documentation, including technical, financial, and administrative reports; prepare justifications; appropriately acknowledge sponsor support; and ensure compliance with other sponsor requirements.

With respect to specific activities, the PI is responsible for:

1) Initiation of all forms and paperwork associated with personnel actions, including hiring documents, certification of time worked, evaluation of performance according to university procedures, and recommendations for retention, promotion, demotion and salary adjustments and increases.

2) Authorization of all project expenditures, assuring that these expenditures are both reasonable and necessary for the project’s conduct and allowable under the terms of the award.

3) Verification of the accuracy of the project’s accounting inputs through a system of on-going monitoring of monthly ledgers and verification of goods and services received on behalf of the project and reported monthly to the Office of Sponsored Programs.

4) Proper care, maintenance and disposition of all equipment purchased with grant/contract funds.

5) Approval of travel by all project personnel (except their own) and others traveling on behalf of the project. This approval verifies that the travel is necessary for the project’s conduct and is in accordance with the funding agency award. Additionally, the PI is responsible for securing other approvals as necessary; e.g., a department chair’s approval for faculty traveling during the period of an academic teaching assignment. Please note that all travel is to be approved by the Office of Sponsored Programs prior to being submitted to the travel office.

6) Selection and hiring of consultants for the project. This is to be done in accordance with the University’s requirements and in a manner to assure that no conflict of interest occurs in any situation.

The PI’s Chair and Dean, Director, or other administrative supervisors share the responsibility of assuring academic integrity and compliance with University procedures insofar as they provide oversight of all the activities conducted by employees of the University.

**Responsibilities of the Vice President for Institutional Effectiveness:**

It is the responsibility of the Vice President for Institutional Effectiveness to provide support to the Institutional Review Board (IRB) and to exercise administrative oversight for this process, and to insure that all human subject research complies with the University’s and other regulatory agencies assurances for protecting the rights and welfare of human subjects. The Vice President for Institutional Effectiveness receives copies of the approved IRB minutes and of
correspondence related to 1) audit results; 2) issues of noncompliance; 3) unanticipated problems involving risks to participants or others and 4) suspensions or terminations of IRB approval. In addition, the Vice President for Institutional Effectiveness is the Institutional Signatory Official. The Institutional Signatory Official’s responsibilities include:

1. Appoint IRB Chair and members.
2. Ensure that necessary resources are allocated to the human research protection program to assure its success.
3. Report all incidents deemed to be serious or continuing noncompliance to the appropriate federal authorities as required by NSU’s Federal wide Assurance and in coordination with general counsel and the Director of Corporate Compliance.
4. Complete all training requirements for the protection of human research participants, and for HIPAA.
5. Receive regular communication regarding the status of the human research protection program and, as necessary, individual studies.
6. Meet regularly with IRB Chair and senior human research protection program leadership.

**Institutional Review Board (IRB) Responsibilities:**

**Responsibilities of the Institutional Review Board (IRB) Chair:**

1. Conduct IRB meetings in accordance with the requirements of applicable federal regulations and NSU policies and procedures; preside over meetings of the fully convened IRB and ensure that the IRB carries out its duly authorized responsibilities as required by federal regulations, ethical principles, state laws and NSU policies and procedures.
2. Reviews the Center Representative’s decision regarding the level of review that applies to a research project and amend it if necessary.
3. Review and approve protocol submissions that qualify for expedited review pursuant to federal regulations, ethical principles, state laws and University policies, or delegate such authority to a qualified and experienced IRB member to conduct such review and approval.
4. Along with the Vice President of Institutional Effectiveness, review any appeals of IRB decisions and determine whether the decision should come before the full board for reconsideration.
5. Ensure that membership of the IRB is recruited, appointed and oriented such that the IRB is duly qualified to fulfill its obligations to review, require modifications to, approve (or disapprove) research protocols that represent the breadth of research submitted to the IRB by NSU researchers.
6. Ensure that reports related to safety, noncompliance, unanticipated problems in research and adverse events are reviewed, attended to and reported pursuant to federal regulations, state laws and University policy.
7. Respond to local and federal investigations relating to protocols and actions, as required.
8. In conjunction with the Vice President of Institutional Effectiveness, the Office of the Provost, General Counsel, the NSU Deans and others as appropriate, develop and revise IRB policies, procedures and guidelines to stay current with regulatory changes and national best practice standards.

**Responsibilities of the Institutional Review Board (IRB):**

The IRB leads the Nova Southeastern University’s human subjects protection program and has full jurisdiction over all research conducted with human subjects by NSU faculty, staff, or students, whether funded or unfunded. The IRB has full authority to disapprove, modify, or approve studies in keeping with ethical and sound research design and in adherence to the guiding principles of the IRB, which include the Belmont Report and by 45 CFR Part 46, 21 CFR Part 50, and 21 CFR Part 56. The IRB operates under the administrative oversight of the Vice President for Institutional Effectiveness. The IRB’s responsibilities include:

1. Ensure that IRB membership is in compliance with all applicable federal regulations and NSU IRB policies and procedures.
2. Maintain the university’s Federal Wide Assurance (FWA) in good standing with the Office of Human Research Protections (OHRP) and maintain and report current membership roster information to the OHRP.
3. Review all research activities of the university involving human subjects, whether funded or unfunded, and document its findings regarding ethical considerations, scientific merit, and adherence to federal regulations and IRB policies and procedures.
4. Provide the appropriate level of review, oversight and monitoring of the research as provided by NSU’s policies and procedures, federal regulations, and state and local laws relative to the review of human subjects research studies;
5. The IRB Center Representative (CR) is responsible for recommending the level of review that applies to a given research project;
6. Ensure compliance with NSU’s policies and procedures, federal regulations, and state and local laws relative to the review of human subjects research studies;
7. Review research activities to ensure that:
   a. Risks to subjects are minimized;
   b. Risks to subjects are reasonable in relation to anticipated benefits;
   c. Selection of subjects is equitable;
   d. Informed consent is obtained or appropriately waived from all prospective subjects and documented;
   e. The research protocol includes a plan for data and safety monitoring;
   f. Subjects' privacy and confidentiality are protected; and
   g. Appropriate additional safeguards are incorporated for any vulnerable subjects.
8. Determine whether the proposed research meets the requirements of all applicable federal regulations, and NSU policies and procedures;
9. Review research protocols and has the authority to
a. Approve;
b. Require modifications to secure approval;
c. Disapprove; and
d. Terminate or suspend the research.

10. Conduct continuing reviews of approved research in accordance with applicable federal regulations and NSU policies and procedures.
11. Review proposed amendments to approved research in accordance with applicable federal regulations and NSU policies and procedures.
12. Review reports of adverse events and protocol deviations in a timely manner, recommend corrective actions or substantive changes if necessary, and notify any applicable regulatory agency in accordance with federal regulations and NSU policies and procedures.
13. Investigate allegations of non-compliance promptly and expeditiously and report to applicable regulatory agencies, administration, investigators, and/or sponsors in a timely manner. Full convened board reviews serious and/or continuing non-compliance events and votes on appropriate corrective action.
14. Has the authority to:

a. Require research progress reports;
b. Audit and/or monitor the research and researchers for adherence to the federal regulations, and IRB policies and procedures;
c. Verify compliance with IRB approved protocols from sources other than investigators as provided in the applicable federal regulations and NSU policies and procedures;
d. Report suspensions, terminations, and non-compliance to IRB officials, institutional officials, and granting agencies; and
e. Report to the appropriate institutional officials and, for research governed by any federal agency, any serious or continuing adverse events, unanticipated problems or investigator noncompliance with the requirements and determinations of the IRB.

15. IRB members complete all training requirements and stay informed of current research-related and regulatory developments.
16. Document that reviews are conducted according to applicable regulations, policies, and procedures;
17. Provides instruction and information to investigators engaged in research involving human subjects;
18. Develops NSU IRB policies, procedures, and guidance regarding human subjects research as required by federal regulations and in accordance with NSU IRB policies and procedures;
19. Adjudicate differences and reviewing problems arising in research involving human subjects.
Responsibilities of the Institutional Review Board (IRB) Staff:

IRB Staff is composed of administrative and professional staff that support and facilitate the IRB process.

1. With the IRB, ensure compliance with the Terms of NSU's Federal Wide Assurance (FWA).
2. Ensure compliance with NSU’s policies and procedures, federal regulations, and state and local laws relative to the review of human subject research studies.
3. Provide guidance regarding the interpretation of regulations, laws, and policies to researchers, staff, and NSU administrators.
4. Develop and implement NSU's human subject protection policies and procedures.
5. Perform audits and/or monitoring of research protocols and investigates matters of non-compliance. Implement corrective action(s) as needed in accordance with federal regulations, NSU policies, and IRB policies and procedures.
6. Provide human subjects protection training for investigators, key study personnel, IRB members, and IRB staff.
7. Complete all training requirements and stay informed of current research-related and regulatory developments.
8. Monitor federal regulatory websites and other research-related resources to stay current with regulatory changes in human subject protection guidelines and policies. Communicates pertinent information to other IRB staff, IRB members, and investigators in a timely manner.
9. Document meeting attendance, votes, reviews and decisions in the meeting minutes as required by applicable federal regulations and NSU policies and procedures.
10. Notify PIs in writing of decisions made at IRB meetings where the PI’s protocol is being reviewed for initial, continuing, or amendment review.
11. Provides copies of each month’s meeting minutes including a listing of all expedited review approvals to IRB members.
12. Maintain IRB records, including IRB meeting minutes, and study-related documentation in accordance with NSU policies, IRB policies, and federal regulations.