NSU NOVA SOUTHEASTERN UNIVERSITY

Research and Sponsored Programs

Division of Responsibilities

NOVA SOUTHEASTERN UNIVERSITY

RESEARCH AND SPONSORED PROGRAMS

DIVISION OF RESPONSIBLITIES

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Vice President of Research & Technology Transfer

The responsibilities of the Vice President of Research & Technology Transfer and Research Integrity Officer (RIO) 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;

5. Administrative oversight to the Grant Lab and is responsible for functions and regulations associated with proposal development and grant writing;

6. As the Research Integrity Officer:

    a. Provide institutional oversight for adherence to protocols and policies for research involving live animals as subjects, in collaboration with the Environmental Health and Safety Committee, the Institutional Animal Care and Use Committee (IACUC), Biosafety and Radiation Safety Committee;

    b. Conduct reviews of on-going projects that use animals and human subjects to ensure adherence with federal and state regulations;

    c. Oversee the development and implementation of policy(s) for research involving recombinant DNA, infectious agents, and biological toxins, working with the Environmental Health and Safety Committee to ensure

compliance with various federal laws and regulations relating to research activities including but not limited to:

i. Institutional Animal Care and Use Committee (IACUC): The Animal Welfare Committee supervises all vertebrae animal use at NSU as required by Federal regulations to ensure all practices are humane and in compliance with the law. www.nova.edu/ehs;

ii. Biosafety: The Biosafety reviews and approves the use of recombinant DNA and other biohazardous agents in research activities; and

iii. Radiation Safety Committee: The Radiation Safety Committee reviews and approves the use of radioactive materials. The Radiation Safety Committee reviews and approves protocols with radiation use involving human subject research, and approves use of radioactive drugs by human subject research enrolled in an approved IRB protocol;

8. The Vice President for Research and Technology Transfer/RIO is the chief institutional official responsible for the direction and guidance of the University's research mission and is responsible for policy formulation and oversight related to the research process and communication, awareness, education and training, in the responsible conduct of research at Nova Southeastern University. In addition, the Vice President for Research and Technology Transfer/RIO in association with the Assistant Vice President for Research and Technology Transfer will implement and administer training pertaining to federal agency requirements and applicable federal and state requirements and monitoring activity related to research compliance activities;

9. Maintain and update as required the Financial Conflicts of Interest in Sponsored Programs policy #16, Office of Sponsored Programs (www.nova.edu/ogc/forms/compliance_conflict_interest.pdf). The Vice President for Research and Technology Transfer is the designated University official for review of financial disclosures by Investigators and for determining whether any significant financial interest is related to the sponsored program and, if so, whether a financial conflict of interest exists;

10. The Research Integrity Officer (RIO) will also have primary responsibility for implementation of the institution's policies and procedures on research misconduct. (Please see the NSU Faculty Policy Manual, Research Misconduct and Office of

Sponsored Programs policy #17, Compliance/Award Acceptance Misconduct in Science);

11. Responsibilities related to Research Misconduct and research integrity includes, but is not limited to:

    a. Update as required, 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; and

    d. Development of a Research Advisory Committee [RAC]. The RAC will also address issues related to implementation and operation of the University's Research Integrity Plan. The Research Advisory Committee shall include but not be limited to the University's above referenced Research Oversight Committees; Vice President for Finance; Office of Sponsored Programs; and Technology Transfer;

    e. Development, implementation, and oversight of the Research Integrity Plan. The Research Integrity Plan provides guidance to the NSU research community and support to the University research oversight committees, boards and offices. The Research Integrity 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 Integrity Plan will provide guidance to the University research community regarding responsible conduct of research. Provide educational programs for researchers in relation to Research Integrity Plan;

    f. Review and respond to internal or external reports of alleged research non-compliance or research misconduct and where appropriate in conjunction with the Provost and General Counsel; and

g. Ensure adherence with all applicable local, state, and federal record maintenance and retention laws and regulations, as well as the sponsor's record retention and maintenance policies and University policies.

Office of Sponsored Programs

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

1. 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;

2. Receive Conflict of Interest Disclosures and refer them to the Vice President of Research and Technology Transfer for review;

3. In cooperation with the Vice President for Finance, Grant Writing Laboratory and other supporting departments, provide researchers and staff training on pre- and post-aware research administration topics; and

4. Conduct periodic internal reviews of sponsored programs.

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 preparation of pre-proposal or proposal;

5. 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;
6. Review budgets for correct application of facility and administrative (indirect) cost rates and obtain signed waivers when full facility and administrative cost recovery will not be realized;
7. Review and submission of proposals;
8. Completion of assurances/certifications;
9. Resolution of compliance issues;
10. Coordination of contract/subcontract review by university legal counsel;
11. Negotiation and acceptance of award;
12. Review and validate appropriate support documentation for cost sharing;
13. Facilitate and monitor Principal Investigator's compliance with programmatic reporting requirements as established by Federal and State law, agency regulations, NSU policies and procedures for sponsored projects awarded to NSU;
14. Verify that IRB, IACUC, Biosafety and Radiation Safety approvals, if applicable, have been applied for or obtained;
15. Review the Proposal Approval Record for completeness and accuracy and verify effort and budgetary commitments; and
16. Accept the project budget and notify the Principal Investigator of the project terms and conditions.
Post-award Functions:
1. 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;

2. Review 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;

3. Establish internal budgets for entry into the Banner financial system;

4. Review subcontractor invoices for reasonableness and compliance with prior approval and cost sharing requirements before approving invoices for payment;

5. Ensure compliance with cost sharing commitments on sponsored projects;

6. Process prior approval requests when sponsor has delegated the authority to submit requests to other University offices or the sponsor when necessary;

7. 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;

8. 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 is made in the payroll system within 30 days of the close of the certification period;

9. Complete and execute all certifications required by the Office of Sponsored Programs;

10. Complete various reviews, required and ad hoc reports, corrective actions, etc. related to post-award activities;

11. Monitor sponsored program_accounts for re-budgeting, overdrafts and budget compliance in cooperation with the Office of Vice President for Finance;

12. Receive and archive final financial reports and invoices prepared by the Office of Vice President for Finance;
13. Request no-cost extensions and changes in Principal Investigator or scope of work from sponsor, in collaboration with the Principal Investigator; and
14. Ensure adherence with all applicable local, state, and federal record maintenance and retention laws and regulations, as well as the sponsor's record retention and maintenance policies and University policies.
15. Issue the Project Digest.

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. The responsibilities include but are not limited to:

1. All studies must have a budget that is shared with the Office of Clinical Research for review;
2. The Office of Clinical Research shall review all preliminary budgets submitted by researchers for consistency with cost principles and inclusion of all costs for research tests and procedures, facilities and administrative costs;
3. Document anticipated pro forma revenue and expenses on a per-subject and per-study basis;
4. Prepare accurate coverage analysis (e.g. Medicare Coverage Analysis) such that the University can bill appropriately for clinical research tests and procedures;
5. Coordinate contract/subcontract review by university legal counsel;
6. Assist with regulatory documents including IRB submission and Informed Consent document;
7. Work with center/college financial representative and PI to establish accounting for study;
8. Submit documents to central finance office to establish banner account;
9. Conduct periodic reviews of on-going clinical trials to ensure adherence with federal and state regulations;
10. Provide researchers and staff training in the proper conduct of clinical research;

11. Develop, implement and maintain Standard Operating Procedures for Good Clinical Practices;
12. Maintain a master list of all on-going and closed clinical research at the University;
13. Prepare study synopsis and submit to malpractice carrier for liability coverage; and
14. Ensure adherence with all applicable local, state, and federal record maintenance and retention laws and regulations, as well as the sponsor's record retention and maintenance policies and University policies.

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, subcontract 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 (or when necessary, outside counsel's 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, and review relevant risk areas to ensure consistency with applicable laws and regulations, as well as institutional research integrity operations, functions and policies. The Assistant Vice President for Research and Technology Transfer will provide the Vice President 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 Vice President for Research and Technology Transfer will consult with General Counsel pertaining to any state or federal regulatory issues at her discretion.

The Assistant V.P. will also 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.

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

1. have a monetary obligation in excess of $15,000;

2. are for a term of more than one (s) year; or

3. 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 President or his executive level designee, and the Vice President of Research and Technology Transfer or the 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 of the Controller's Office and the Risk Management Office:

Controller's Office:

The responsibilities of the Controller's Office are as follows:

1. Provide an effective accounting system to properly record and track the income, expense, assets and liabilities of the University. The accounting system will allow for an effective means to monitor compliance with fiscal and reporting requirements for all restricted funds as established by Federal and State law, agency regulations, and NSU policies and procedures for sponsored projects awarded to NSU;

2. Conduct annual review to determine whether or not Cost Accounting Standards Board Disclosure Statement must be completed; complete and maintain as appropriate;

3. Submit and negotiate the Facilities and Administrative (F&A) cost rate with NSU's cognizant agency;

4. Exercise administrative oversight of the Office of Contract and Grant Accounting; and

5. Monitor clinical research accounts, in cooperation with the Office of Clinical Research, college/center finance representative(s), and the Principal Investigators (PIs); including review for re-budgeting, overdrafts, and compliance as well as coordinating with the PIs to conduct periodic review of clinical research charges to validate that no unallowable or unrelated costs were charged in error.

Office of Contract and Grant Accounting:

The Office of Contract and Grant Accounting (CAG) has the following responsibilities:

1. Monitor sponsored programs accounts for re-budgeting, overdrafts, and compliance in cooperation with the Office of Sponsored Programs and the Principal Investigators (PIs);
2. Coordinate with PIs to conduct periodic review of charges to sponsored awards to validate that no unallowable or unrelated costs were charged in error;
3. Manage and allocate indirect cost funds collected by NSU in accordance with agency awarding documents and NSU policies and procedures;
4. Coordinate the annual A133/Single Audit conducted by the external audit firm engaged by the University;
5. Prepare the Schedule of Expenditures of Federal Awards and State Financial Assistance and Data Collection Form as required for compliance with A-133;
6. Prepare periodic expenditure reports for PDs/PIs and follow up with PDs/PIs regarding their rate of expenditures as compared to budget;
7. Prepare and submit financial reports and invoices;
8. Review and approval of all invoices on grants and contracts not completed by accounting;
9. Establish effective cash management systems to ensure proper and timely cash flow for all sponsored project accounts including timely deposits of contract and grant receipts from sponsors, follow up with sponsors on delinquent payments, and drawdown of funds in a timely manner;
10. Complete timely fiscal close-out of grants and contracts;

11. Complete various reviews, required and ad hoc reports, corrective actions, etc. related to accounting activities;

12. Send a copy of all final financial reports and invoices prepared by the Office of Contract and Grant Accounting and submitted to the funding agency, to the Office of Sponsored Programs;

13. Ensure adherence with all applicable local, state, and federal record maintenance and retention laws and regulations, as well as the sponsor's record retention and maintenance policies and University policies as it relates to accounting records; and

14. Approve expenditure for cost transfer requests. Maintain written justifications for cost transfers and provide justifications upon requests to internal and external auditors.

Risk Management Office:

It is the responsibility of the Director, Risk Management to handle all sponsored project and research related insurance requirements as follows:

Pre-Award Functions:

1. Inbound and outbound contract/subcontract review and negotiation of sponsor insurance requirements;

2. Confirm sponsored project covered on University insurance programs as required by sponsor; and

3. Issue certificates of insurance/proof of insurance if required.

Post-award Functions:

1. Issue certificates of insurance as required; and

2. Contract/subcontract amendment review, when applicable, and negotiation of sponsor insurance requirements.

Claims Handling Functions:

1. Oversee claims handling process if an accident, injury or adverse event involving a participant/patient/student occurs (on-campus or off-campus). Policy may be found at http://www.nova.edu/cwis/fop/risk/accidents.html;

2. Oversee claims handling process if an accident, injury or adverse event involving an employee occurs (on-campus or off-campus). Policy manual may be found at http://www.nova.edu/cwis/fop/risk/policies.html; and

3. Oversee claims handling process if an exposure involving an employee occurs (on-campus or off-campus). Policy may be found at http://www.nova.edu/cwis/fop/risk/post_exposure.html.

Vice President for Compliance and Chief Integrity Officer

It is the responsibility of the Vice President for Compliance and Chief Integrity Officer to exercise administrative oversight to the Office of Compliance Coordinators and is responsible to the University for the following responsibilities:

1. Oversee compliance monitoring process of internal and external reviews of federal healthcare program healthcare service coding and documentation associated with research and sponsored programs;

2. Review relevant risk areas of federal healthcare program healthcare service coding and documentation associated with research and sponsored programs and are consistent with applicable laws and regulations;

3. Develop training programs pertaining to federal healthcare program healthcare service coding and documentation and HIPAA Privacy and Research associated with research and sponsored programs;

4. Conduct periodic internal audits and direct and assist with external audits of federal healthcare program healthcare service coding and documentation associated with research and sponsored programs;

5. Review and respond to internal or external reports of alleged federal healthcare program coding and documentation and HIPAA Privacy non-compliance;

6. Work with legal counsel to develop methods of investigation of alleged federal healthcare program coding and documentation and HIPAA Privacy non-compliance;

7. Coordinate with General Counsel the self-reporting of any identified violations of federal healthcare program healthcare service coding and documentation requirements;

8. Maintain the University Compliance Hotline and facilitate/triage employee questions by coordinating/directing them to University departments and/or individuals as appropriate; and

9. Coordinate with General Counsel and Internal Auditor the self-reporting of any identified violations of research and sponsored programs federal requirements.

Dean/College

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:

1. The Dean is responsible for ensuring that faculty and staff has thorough knowledge, training, and understanding of the policies and procedures for the proper management of contract and grant proposals, awards, and reporting;

2. Review the proposal in a timely manner and indicate approval of the proposal by signing the Proposal Approval Record. By signing, the Dean indicates that the commitments to the project are acceptable, that personnel, space and facilities are available to conduct and support the project as proposed, and that the project is appropriate to the goals and objectives of the college or departments;

3. Ensure consistency in budgeting of direct costs vs. facilities and administrative (F&A) costs (pre-award phase);

4. Ensure consistency in charging of direct vs. F&A costs (pre-audit function);

5. 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;

6. 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);

7. Award document and any regulations cited therein;

8. 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;

9. 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;

10. Prevent budget overdrafts;

11. Ensure all adjustments to expenditures are performed timely;

12. Review subcontractor costs for reasonableness and compliance with prior approval and cost sharing requirements before processing invoices for payment;

13. 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;

14. Provide timely account close-out notices and timely processing of close-out adjustments as per the project digest;

15. Ensure all technical reports are completed and submitted on a timely basis;

16. Obtain and retain appropriate support documentation for financial transactions within one (1) year of close of contract, grant or sponsored project;

17. Oversee cost sharing and matching commitments or other support from sources inside and outside the school or college;

18. Administer counseling or discipline as appropriate in matters of noncompliance; and

19. Ensure adherence with all applicable local, state, and federal record maintenance and retention laws and regulations, as well as the sponsor's record retention and maintenance policies and University policies.

Principal Investigator (PI)

PI's on approved sponsored programs, including but not limited to federally funded and non-federally funded grants and human subjects research, responsibilities and activities include the following:

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:

    a. the proposed sponsored project has academic merit;

    b. the proposed sponsored project is consistent with the overall academic interests of the department(s); and

    c. 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, and the PI will obtain additional approvals, including from affiliated institutions or collaborating departments or colleges, when required;

4. Prepare, or directly supervise the preparation of the Proposal Approval Record for sponsored programs including but not limited to federally funded and non-federally funded grants and human subjects research, and submit the Proposal Approval Record to meet internal and external deadlines. The PI will indicate through his or her signature on the Proposal Approval Record that the information and content in the Proposal Approval Record is true, accurate and complete, that the budget reflects all appropriate expense items, that the project will be performed in compliance with

university and sponsor policies, if funded, and that the PI will obtain all necessary approvals related to human subjects, animals, or biosafety, if applicable to the project, before beginning any research activities;

5. The budget for the proposed program will be adequate for the work proposed, including allowances for contingencies and salary increases, and will apply the correct indirect cost rate and base. 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. If any cost sharing will be committed to the proposal, the PI must complete the Cost Sharing Approval form; Proposal Approval Record part B];

6. The proposed award will comply fully with university administrative regulations and academic policies, and the PI will prepare the appropriate forms and applications to applicable review boards/committees, such as those regarding employment and employee relations, safety, safeguards to human subjects in research, fiscal and purchasing procedures, and animal care;

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

8. 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;

9. 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;

10. Identify the need for subcontracts;

11. The PI who accepts funds from a sponsor in support of research will comply with the university's policy on "Conflict of Interest;"

12. 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, and meeting the terms and conditions of the award;

13. 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, and where applicable the Office of Clinical Research, 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;

14. The PI will take part in, and ensure that his or her staff takes part in, required and voluntary education and training programs offered by the University, professional organizations, and regulatory agencies in order to be thoroughly knowledgeable about the conduct of research, including but not limited to CITI training required for all human subject research and financial conflict of interest;

15. The PI is responsible for conducting or supervising the conduct of human-subjects research and for protecting the rights, safety, and welfare of the subjects enrolled in the research;

16. The PI must ensure that all human-subjects' research is conducted in an ethical manner and in accordance with all federal, state, and local laws and regulations, institutional policies, and requirements or determinations of the IRB;

17. The PI may delegate study-related tasks, but must adequately supervise study personnel to whom tasks are delegated. When supervising the conduct of human-subject's research, the PI must ensure that:

    a. Study personnel are qualified by training and experience to perform study related tasks that have been delegated to them;

    b. Study personnel have an adequate understanding of the research; and

    c. Study personnel follow the IRB-approved protocol, including the recruitment and consent procedures described in the protocol summary;

18. When tasks are delegated by the PI, the PI is responsible for providing adequate supervision of those to whom tasks are delegated and the PI is accountable for violations resulting from failure to adequately supervise the conduct of the study.

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 and purchases, assuring that these purchases and expenditures are both reasonable and necessary for the project's conduct and allowable under the terms of the award. Obtain additional sponsor approval for expenditures, when required;
3. Initiate requests for re-budgeting per sponsor requirements and work with the Office of Sponsored Programs and/or the Office of Clinical Research where applicable to review the award document to determine if prior approval by the sponsor is required;
4. Prior to submission to the Dean for review, the P.I. shall review subcontractor costs for reasonableness and compliance with prior approval and cost sharing requirements;
5. Notifying the Director of the Office of Sponsored Programs and/or the Administrative Director of the Office of Clinical Research where applicable with a contact person's name when planning to be absent from the project for more than 30 days;
6. Notifying the Dean and the Director of the Office of Sponsored Programs and/or the Administrative Director of the Office of Clinical Research where applicable of a proposed change in Principal Investigator to initiate the required correspondence in accordance with sponsored research procedures;
7. Notify the Office of Sponsored Programs and/or the Administrative Director of the Office of Clinical Research where applicable of any impending transfer of a grant or contract to another institution; the Office of Sponsored Programs and/or the Office of Clinical Research where applicable will assist with the transfer in accordance with sponsor requirements;

8. Review periodic expenditure reports, monitor encumbrances and expenditures and communicate with Office of Contract and Grant Accounting, college/center finance representative(s) and NSU Controller's Office as needed;

9. Initiate budget transfer requests as appropriate with Office of Sponsored Programs and/or the Office of Clinical Research where applicable;

10. Initiate cost transfers and correcting entries in coordination with the Office of Contract and Grant Accounting, college/center finance representative(s) and NSU Controller's Office as needed;

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

12. 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 and/or the Office of Clinical Research where applicable prior to being submitted to the travel office;

13. 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;

14. Preparing the final programmatic (technical) narrative report and adhere to sponsor deadlines;

15. Ensuring the integrity and protection of notebooks and scientific data, and adherence with all applicable local, state, and federal record maintenance and retention laws and regulations, as well as the sponsor's record retention and maintenance policies and University policies;

16. Ensure that the NSU IRB approval is obtained prior to initiation of the research;

17. Ensure that the research is conducted in accordance with the NSU IRB-approved protocol, including, where applicable, the approved recruitment;

18. When informed consent is required, informed consent is obtained prior to the initiation of any study-related procedures;

19. When written informed consent is required, informed consent is obtained and documented using the current NSU IRB-approved research consent form;

20. When drugs, biological products, and devices are being investigated or used, they are managed and controlled as required by institutional policy and, when applicable, FDA regulations 21 CRF 312 and 21 CFR 812;

21. Unanticipated problems involving risks to subjects or others (including adverse events) are reported promptly to the NSU IRB in accordance with NSU IRB policy;

22. When applicable, Data and Safety Monitoring Board/Data Monitoring Committee or other monitoring group reports are submitted promptly to the NSU IRB for review;

23. Continuing review is conducted prior to expiration of NSU IRB approval in accordance with NSU IRB policy;

24. Should NSU IRB approval lapse, research procedures, such as recruitment and enrollment of subjects, study procedures on currently enrolled subjects, review of health/medical records, collection of tissue or other samples, or analysis of data, are not conducted until the NSU IRB re-approves the research or until special permission is obtained from the NSU IRB to continue previously enrolled subjects because it is in their best interests to do so;

25. When the research has been completed or is being closed out prior to completion, a final closing report is submitted to the NSU IRB;

26. Adequate and accurate research records are kept and retained as required by the NSU IRB and, when applicable, by the sponsor or FDA;

27. Research records are made available to the NSU IRB, the sponsor, and when applicable, the Office for Human Research Protections (OHRP), and the Food and

Drug Administration (FDA) upon request for monitoring and oversight of the research; and

28. PIs are responsible for:

a. adhering to the University's policies and procedures pertaining to research projects involving Protected Health Information (PHI) and electronic Protected Health Information (ePHI) (hereinafter referred to as PHI);

b. ensuring that PHI is accessed and used only by authorized research personnel for approved research activities;

c. ensuring the secure storage of PHI;

d. ensuring the secure transmission of PHI;

e. meeting federal, legal and University requirements for disposal of PHI;

f. reporting breaches of confidentiality related to PHI;

g. accounting of disclosures, as required by HIPAA; and

h. ensuring that all members of the research team have completed the University HIPAA Privacy, Security and Research Training(s) as required.

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.

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. Reports cases of serious and/or continuing non-compliance to applicable funding agencies in the case of a sponsored project, the Food and Drug Administration (FDA) (when applicable), and the Office for Human Research Protection (OHRP) and where applicable in conjunction with the General Counsel and Director of 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; and
7. Ensure adherence with all applicable local, state, and federal record maintenance and retention laws and regulations, as well as the sponsor's record retention and maintenance policies and University policies.

Institutional Review Board (IRB)

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 on any protocol identified by the Director as a result of the Director's routine review of exempt studies;

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, unanticipated problems in research and adverse events are reviewed, attended to and reported pursuant to federal regulations, state laws and University policy;

7. In collaboration with the IRB Director, investigates allegations of non-compliance and protocol deviations, and determines if the non-compliance is serious and/or on-going, and refers cases of serious and/or ongoing non-compliance to the full Board for review and corrective action;

8. Respond to local and federal investigations relating to protocols and actions, as required; and

9. In conjunction with the Vice President of Institutional Effectiveness, the Office of the Provost, General Counsel, the NSU Deans, the IRB, the IRB Director 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 each member of the IRB is in compliance with all applicable federal regulations and NSU IRB policies and procedures;

2. Review all funded and unfunded research activities of the university involving human subjects, and document its findings regarding ethical considerations, scientific merit, and adherence to federal regulations and IRB policies and procedures;

3. 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;

4. The IRB Center Representative (CR) is responsible for recommending the level of review that applies to a given research project;

5. Ensure compliance with NSU's policies and procedures, federal regulations, and state and local laws relative to the review of human subjects research studies;

6. 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 (if applicable);
f. Subjects' privacy and confidentiality are protected; and
g. Appropriate additional safeguards are incorporated for any vulnerable subjects;
7. Determine whether the proposed research meets the requirements of all applicable federal regulations, and NSU policies and procedures;
8. 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;
9. Conduct continuing reviews of approved research in accordance with applicable federal regulations and NSU policies and procedures;

10. Review proposed amendments to approved research in accordance with applicable federal regulations and NSU policies and procedures;
11. Review reports of adverse events 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;
12. Review and investigate where appropriate allegations of non-compliance and report serious and continuing non-compliance issues to appropriate University supervisors (e.g. Deans and Program Directors), the Institutional Officer/Vice President of Institutional Effectiveness, granting agencies (where appropriate) and federal agencies. Full convened board reviews serious and/or continuing non-compliance events and votes on appropriate corrective action;
13. 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;
14. IRB members complete all training requirements and stay informed of current research-related and regulatory developments;

15. Document that reviews are conducted according to applicable regulations, policies, and procedures;

16. Provides instruction and information to investigators engaged in research involving human subjects;

17. Develops, maintains, and reviews as needed NSU IRB policies, procedures, and guidance regarding human subjects research as required by federal regulations and in accordance with NSU IRB policies and procedures;

18. Adjudicate differences and reviewing problems arising in research involving human subjects; and

19. Ensure adherence with all applicable local, state, and federal record maintenance and retention laws and regulations, as well as the sponsor's record retention and maintenance policies and University policies.

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. 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. In collaboration with the Vice President for Institutional Effectiveness and IRB Chair, investigate allegations of non-compliance promptly and expeditiously. Non-compliance that is determined by the Director as being serious and/or continuing will be reviewed by the full convened Board, which will vote on appropriate corrective action. The IRB Director or designee will report the Board's decision in writing to the Principal Investigator, the researcher's immediate supervisor, the signatory office, the Director of the Office of Sponsored Programs (in the case of funded research), and the Administrative Director of the Office of Clinical Research in the case of a clinical trial). The IRB Director, in collaboration with the IRB Chair or an

IRB member who serves as his/her designee, has discretion to take corrective actions for non-compliance issues that are neither serious nor continuing;
4. With the IRB, ensure compliance with the Terms of NSU's Federal Wide Assurance (FWA);
5. Ensure compliance with NSU's policies and procedures, federal regulations, and state and local laws relative to the review of human subject research studies;
6. Provide guidance regarding the interpretation of regulations, laws, and policies to researchers, staff, NSU administrators and the IRB;
7. Develop and implement NSU's human subject protection policies and procedures;
8. 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;
9. Provide human subjects protection training for investigators, key study personnel, IRB members, and IRB staff;
10. Complete all training requirements and stay informed of current research-related and regulatory developments;
11. 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;
12. Document meeting attendance, votes, reviews and decisions in the meeting minutes as required by applicable federal regulations and NSU policies and procedures;
13. Notify PIs in writing of decisions made at IRB meetings where the PI's protocol is being reviewed for initial, continuing, or amendment review;
14. Provides copies of each month's meeting minutes including a listing of all expedited review approvals to IRB members;

15. Maintain IRB records, including IRB meeting minutes, and study-related documentation in accordance with NSU policies, IRB policies, and federal regulations; and

16. Conducts a routine review of studies that are determined to be exempt by the Center Representatives and bring any study that may not meet the federal guidelines of exempt research to the attention of the Chair for his/her review.

Executive Director of Internal Audit

The responsibilities of the Executive Director of Internal Auditing include:

1. Oversight of the performance of internal audits in conjunction with General Counsel;
2. Oversight of the performance of internal audits at the request of the Internal Audit Committee, NSU Executive Management and General Counsel;
3. Perform a periodic audit risk assessment of University research and sponsored programs activities;
4. Perform periodic internal audits of selected research and sponsored programs;
5. Scope of the audits include but are not limited to:
    a. Divisions or departments of the University that have substantive involvement with or impact on Federal and/or state programs and on the risk areas identified;
    b. Review of the research and sponsored programs activity may include but are not limited to:
        i. Adherence with applicable laws, regulations and specific grant/contract requirements;
        ii. Confirmation of the existence of required information;
        iii. Time and Effort Reporting;
        iv. Properly Allocating Charges to Award;
        v. Reporting Financial Support From Other Sources;

vi. Program Income;
vii. Monitoring Expenditures;
viii. Subrecipient Monitoring;
ix. Indirect Cost and Fringe Benefit Rate Application;
x. Facilities & Administration (F&A) Costs;
xi. Financial Status Reports; and
xii. Record retention and maintenance;
6. The evaluation of University policies and their adherence and adequacy;
7. Work with General Counsel and the Compliance Officer as appropriate pertaining to the self-reporting of any identified violations of federal or state requirements; and
8. Ensure adherence with all applicable record maintenance and retention laws and regulations, and University policies with respect to internal audit department records and documentation.

Vice President of Clinical Operations

The responsibilities of the Vice President of Clinical Operations include:

1. Ensure compliance with policies and procedures;

2. Ensure that faculty and staff have a thorough understanding of the policies and procedures for the proper management of contract and grant administration, as it pertains to the provision of healthcare services; and

3. Ensure adherence with all applicable local, state, and federal record maintenance and retention laws and regulations, as well as the sponsor's record retention and maintenance policies and University policies.

4. Work collaboratively with the Office of Clinical Research and Principal Investigator to develop a "billing grid" that provides details by visit, service type, CPT and payer. For example:
    - Bill to study/sponsor
    - Bill to participant
    - Drug, device or supply is provided by sponsor

5. Work collaboratively with the Office of Clinical Research and Principal Investigator to code and price research participant/patient care services.

6. Work collaboratively with the Office of Clinical Research and Principal Investigator to ensure that clinical services, items or tests are billed in accordance with the Medicare Coverage Analysis.

7. Work collaboratively with the Office of Clinical Research and Principal Investigator to ensure proper invoicing of sponsors and research participants.

8. Work collaboratively with the Office of Clinical Research and Principal Investigator to ensure that research participant's research related clinical services are billed appropriately and according to applicable regulations.

9. Work collaboratively with the Office of Clinical Research and Principal Investigator

to ensure that charge capture/charge entry is appropriately entered into the clinical information system.
10. Work collaboratively with the Office of Clinical Research and Principal Investigator to ensure that research collections are entered into the applicable research study account.
11. Work collaboratively with Clinical Information Support Services and the Principal Investigator with respect to documentation of research participation in the electronic medical record (e/g/ study demographic information or research care plan entered into each research participant's electronic medical record).

Environmental Health and Safety Board

The responsibilities of the Environmental Health and Safety Board include:

1. The Environmental Health and Safety Board of Advisors is responsible for the development, implementation, and administration of environmental health and safety programs required by federal, state, and local agencies for the NSU community. Activities of this Board include the following programs: Laboratory Safety (including biological safety, chemical hygiene, and radiation safety), Fire and Life Safety, Occupational Safety (including bloodborne pathogens, hazardous chemical handling, and personal protective equipment), and Environmental Safety (including policies for asbestos waste, compressed gas, corrosive waste, drain disposal, empty containers, ignitable waste, medical waste, oil and solvents waste, oxidizing waste, photographic waste, radioactive waste, reactive waste, special waste, toxic waste, and used battery waste);
2. The Environmental Health and Safety Board provides the appropriate educational training and awareness to researchers, support staff, and the University community in the above listed areas;
3. Develop and administer environmental health, safety programs and policies required by federal, state and local agencies to ensure adherence based on the types of activities and research at NSU;
4. Provide institutional support for proposals involving infectious agents, biological toxins, and other potentially hazardous materials;
5. Provide institutional oversight for adherence to protocols and policies for research involving chemical safety, laboratory safety, laser safety, and bio-safety;
6. Conduct audits of on-going projects to ensure compliance with the appropriate federal, state, and local regulations;
7. Implement medical surveillance programs as needed to ensure worker protection during all research activities;

8. Maintain records according to federal, state, and local policies and regulations;
9. Coordinate the pick-up and disposal of identified hazardous chemical waste and biological waste products;
10. Implement a check in/ checkout policy and procedure for all research laboratories to ensure that excess chemicals, unused chemicals, and waste chemicals are handled in an appropriate and legal manner; and
11. Ensure adherence with all applicable local, state, and federal record maintenance and retention laws and regulations, as well as the sponsor's record retention and maintenance policies and University policies.