



## **Operations Manual**

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## **MISSION STATEMENT**

The North Florida Foundation for Research and Education, Inc. (NFFRE) is a private, non-profit entity incorporated on February 25, 1997, in the state of Florida. It is affiliated with, but legally distinct from, the North Florida/South Georgia Veterans Health System (NF/SG) of Gainesville, Florida. Its mission is to support research and education activities of North Florida/South Georgia Veterans Health System. All activities focus on new and better ways of improving the treatment and/or prevention of disease and disability. Accordingly, all funds expended will be relevant to accomplishing this mission. (NFFRE funds may not be used to support activities of other similar organizations without advance review and approval by the Board of Directors.) Federal tax-exempt status (501(c)(3)) was awarded on October 28, 1997 (Federal ID #59-3432918). Funds to support NFFRE activities are derived from disease-focused charitable donations or grants from private individuals, non-profit corporations, for-profit corporations, federal entities and public and

private organizations.

NFFRE's mission is to advance the research and education missions of the NF/SG through the support of research-related and education activities;

NFFRE will accomplish this mission by

- (1) providing a flexible mechanism for the receipt and administration of funds, not directly appropriated to NF/SG, for the conduct of VA-approved research and educational activities,
- (2) making the results of such research available to the scientific and general public by means of research communications in recognized journals widely distributed to libraries and the biomedical community, and by means of scientific lectures and open meetings supported by the foundation, and
- (3) operating in any other manner for such purposes as will qualify it as an exempt organization under 501(c)(3) of the Internal Revenue Code of 1986, as amended, or under any future United States Internal Revenue Law covering distributions to organizations qualified as tax exempt.

## **OVERSIGHT AUTHORITY**

Due to the unique relationship between NFFRE and NF/SG, special regulations have been imposed. In addition to conforming with all applicable State and Federal regulations and laws pertaining to non-profit corporations, NFFRE must also comply with requirements outlined in VA implementing guidance (VHA Handbook 1200.17 or other VHA policy) and Title 38 United States Code (U.S.C.) Sections 7361 through 7366. The nature and scope of these regulations warrant their inclusion in this manual.

## **GENERAL POLICY STATEMENT**

No policy of NFFRE shall be knowingly carried out at variance with Federal, Department of Veterans Affairs, State, or Local authority, or with the common ethical principles of academic medicine. In keeping with this, NFFRE's activities shall not involve monies, income, or any direct personal benefit to its members or Investigators unless it is for services as a director or officer of the corporation, the reimbursement of which is authorized by the Board of Directors.

## **WOC APPOINTMENTS FOR NFFRE EMPLOYEES**

All NFFRE employees must have a VA WOC appointment through the Research Service at the NF/SG prior to actively engaging in NFFRE research or education activities.

Reference Appendix A for procedures regarding WOC Appointments.

## **SCIENTIFIC MISCONDUCT**

Any issues pertaining to scientific misconduct involving a NFFRE administered project will be handled in accordance with DVA regulations.

## **BOARD OF DIRECTORS**

The number of Directors shall be six to twelve (6-12) or such other number as may be designated from time-to-time by resolution of a majority of the entire Board of Directors but shall never be less than six (6). The statutory Directors of the Board shall include the persons holding the positions of Medical Center Director, Chief of Staff, Associate Chief of Staff for Education, and Associate Chief of Staff for Research and Development, NF/SG.

The fifth and sixth additional Statutory Non-Federal Directors of NFFRE shall be persons who are not officers or paid employees of the Federal Government but who are familiar with issues involving medical and scientific research (as required by Public Law 100-322). These Non-Federal Statutory Directors may not be affiliated with, employed by, or have any other financial relationship with any entity that is a source of funding for research by the NF/SG, unless that source of funding is a governmental entity or an entity the income of which is exempt from taxation under section 501(c)(3) of the Internal Revenue Service Code of 1986. These Directors shall routinely serve a one-year term renewable without limits.

The remaining two (2) or more additional Directors may or may not be employees or agents of the Federal Government or NF/SG. They shall serve a one-year term renewable without limits.

In the case of any vacancies on the Board of Directors through death, resignation, disqualification, or removal for other cause of a Non-Statutory Director, the Medical Center Director shall appoint a successor to hold office for the unexpired portion of the term of the Director whose place shall be vacant and until the election of a successor. In the event of a vacancy through the death, resignation, disqualification, removal for other cause of a Statutory VA Director, the person subsequently appointed shall become a Director upon assuming said position. In the interim, the person serving as acting for the position shall serve as a Director. A Non-Statutory Director may be removed from office with or without cause by the Medical Center Director.

A Non-Statutory Director may resign his/her appointment at any time. A Non-Statutory Director may be removed upon the vote of a majority of the Statutory Directors and the approval of the Medical Center Director at a Special Meeting of the Directors called for the purpose of such removal, except that a Statutory Director may be removed only for cause.

### **BOARD REMUNERATION**

With the exception the Medical Center Director, Chief of Staff, Associate Chief of Staff for Education, and Associate Chief of Staff for Research and Development, Board members may receive \$100 for each meeting attended with the following caveat: members who are NF/SG employees must be on annual leave or meeting outside their normal tour of duty. Members eligible for payment are free to donate such payments to NFFRE. Donations will be acknowledged with a letter documenting donation to a nonprofit organization.

### **PRESIDENT. BOARD OF DIRECTORS**

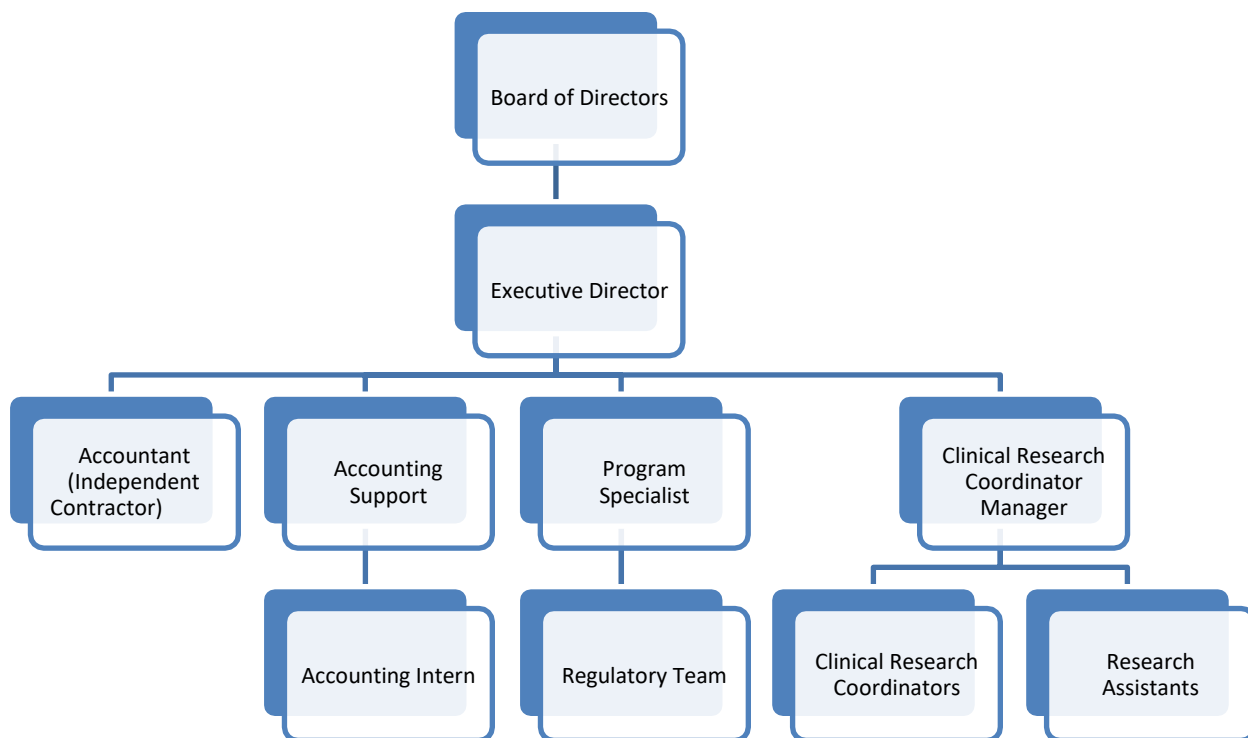
The President, Board of Directors is elected by a majority vote of the Directors. At the Board's discretion, incumbents may serve consecutive appointments. The President, Board of Directors will preside at all meetings of the Board unless a majority vote of a quorum elects a Chairman other than the President, Board of Directors to preside at meetings of the Board. The President, Board of Directors will be an ex-officio member of all standing committees. The President, Board of Directors will cause the necessary notice to be given of meetings of the Board of Directors and the annual meeting ensuring that time requirements as stipulated in the organization's By-Laws are met.

### **EXECUTIVE DIRECTOR**

The Executive Director (ED) is appointed by a majority vote of the Directors with the concurrence of the Medical Center Director. At the Board's discretion, incumbent may serve consecutive appointments. The ED shall be the chief executive officer (CEO) of NFFRE and shall be responsible for general and active management of the business of NFFRE and shall see that all orders and resolutions of the Board of Directors are carried into effect. The ED shall join in the execution of the corporate name on all authorized deeds, mortgages, bonds, contracts, or other instruments, except in the cases in which the signing or execution thereof shall be expressly delegated by the Board of Directors to some other officer or agent of the corporation. The ED shall attend all meetings of the Board of Directors and all annual meetings to see that all of the proceedings of the meetings of NFFRE and of the Board of Directors are recorded. The ED or designated agent(s) authorized by the Board of Directors shall be custodian of all corporate records and papers, have custody of NFFRE funds and securities, ensure that full and accurate accounts of receipts and disbursements are kept in books belonging to NFFRE and shall deposit all monies or other valuable effects in the name and to the credit of NFFRE in such depositories

as may be designated by the Board of Directors. The ED shall disburse the funds of NFFRE as may be ordered by the Board of Directors and shall render to the Board of Directors or Investigators at its regular meetings or when the Board of Directors or Investigators so require, an accounting of all transactions and of the financial condition of NFFRE. The ED shall ensure documentation of recruitment, resignation, termination, appointment, scheduling for training and development, accident reports, Without Compensation (WOC) appointments, and benefits, as well as provide guidance and counseling to employees when required concerning personnel matters. As required by the organization's By-Laws, no Board member may serve as the Executive Director.

Refer to table below for NFFRE organizational chart.



## **INSURANCE**

The Board of Directors is responsible for determining the types and extent of insurance coverage it feels necessary and prudent to protect the operations and personnel of the NFFRE. Specifically, insurance policies obtained are intended to protect Board members, officers, employees, and assets of NFFRE. Insurance needs of NFFRE will be monitored by the ED. Additions or deletions to existing coverage will be reviewed and approved by the Board as the need arises.

## **DIRECTOR'S AND OFFICER'S LIABILITY**

Activities of NFFRE Board of Directors and Officers shall be covered by insurance. The policy shall provide coverage in the amount of \$2,000,000 maximum aggregate limit of liability per all claims made in any policy year or whatever amount the Board deems necessary. The purpose of this policy is to protect Board members and officers from suits or other legal actions brought by employees, individuals, and outside organizations. An example would be wrongful termination of an employee or an alleged breach of duty by a Board member. Board membership mandated by Public Law 100-322 is covered by Federal Torts Claim protection. These members serve on the Board as a function of their Federal position. The cost of Director's and Officer's Liability coverage is absorbed from the Administration account.

## **FIDELITY COVERAGE (BOND)**

This coverage provides protection against acts of employee dishonesty. In addition, it provides protection against forgery and alteration. The amount of coverage purchased will be adjusted as NFFRE balance of funds increases or decreases. The ED will ensure that adequate fidelity coverage is in effect to protect all NFFRE funds. The cost of this fidelity coverage is absorbed from the Administration account.

## **WORKERS COMPENSATION**

NFFRE employees shall be protected against on-the-job injuries by insurance. NFFRE employees perform their duties in a Federal facility in furtherance of NF/SG-approved activities. Coverage is mandatory for all NFFRE-only employees (not applicable to full-time NF/SG employees working part-time for NFFRE). The cost of this insurance is absorbed by the account of the employing participant.

## **UMBRELLA PROTECTION**

This coverage provides an additional \$1,000,000 limit of liability for Workers Compensation claims plus \$1,000,000 for other liability protection. The cost of this umbrella protection coverage is absorbed from the Administration account.

## **EQUIPMENT**

The majority of NFFRE equipment is now managed by the individual research investigators and their staff and located throughout the NF/SG facilities. A Federal facility, NF/SG provides no coverage against loss, theft, or damage since it is considered "self" insured.

## **FUNDING**

Any funds other than VA appropriations may be accepted by NFFRE from a variety of sources, such as, but not limited to, Federal or non-profit agencies engaged in the support of research, commercial organizations involved in the development of new drugs and devices, or personal donations. All checks MUST be made payable and mailed to North Florida Foundation for Research and Education, Inc., 1601 SW Archer Rd., Gainesville FL 32608-1197 for appropriate processing and depositing. Checks made payable to Investigators cannot be endorsed for payment to NFFRE since DVA lawyers have opined that the participant's endorsement constitutes "constructive receipt" of the funds in question. The issue of constructive receipt could create potential legal and tax ramifications for the participant. Accordingly, only checks listing the NFFRE as payee will be accepted. Checks received that are made payable to any other payee will be returned to the appropriate participant. The participant will be responsible for resolving the situation and having the check in question reissued correctly.

NFFRE may accept and use funds donated by "related" persons (board members, investigators, employees, etc.) under the following conditions: (1) there are no limitations or conditions that are onerous or overly burdensome to NFFRE, and (2) additional oversight is provided by the board of directors (e.g., review and approval of all expenditures of the funds) to prevent the occurrence or appearance of personal benefit to the donor.

Unrestricted and restricted donations resulting from fundraising activities and unsolicited gifts will undergo similar scrutiny. The board of directors will determine if the donation/gift is consistent with the purposes of NFFRE and free of onerous or burdensome limitations or conditions. The board of directors will also determine how the funds are to be best utilized by NFFRE.

Currently, NFFRE charges a 30 percent indirect cost rate on all funds accepted from pharmaceutical companies and other private sources for deposit. Transferred General Post Funds will be charged 2.5 percent if indirect cost has already been levied against the funds by the Research Service prior to the transfer to NFFRE. Federal awards will provide for an indirect cost rate derived in accordance with 2.CFR 215. Potential research or education awards that authorize no or a lower indirect cost rate must be reviewed and approved by the President, Board of Directors on a case-by-case basis prior to acceptance. Indirect cost revenues and investment interest will be used to cover NFFRE expenses such as salaries, supplies, accounting fees, insurance costs, administrative staff travel, etc.

Reference Appendix B for procedures regarding Funding.

## **INTELLECTUAL PROPERTY RIGHTS**

Since NFFRE is a Federally authorized non-profit research corporation, private gain by any individual(s) is precluded by Internal Revenue Service regulations. Federal law will prevail in issues related to intellectual property rights. NFFRE will never own intellectual property since it is outside the statutory authority of NFFRE.

## **TRANSFER OF FUNDS**

Investigators who resign their NF/SG positions or who have a change in status that affects their WOC appointments will no longer meet the membership requirements outlined earlier. As a result, any fund balance and/or equipment inventory will be handled according to the appropriate policy. The transfer of funds policy stipulates that no funds will be transferred from NFFRE unless stipulated in a binding agreement. All other fund balances will remain NFFRE's for redistribution at the board's discretion and will be transferred to the unrestricted NFFRE Administration account. The policy also stipulates that no invoices for books, subscriptions, or dues will be paid within 90 days of a participant's anticipated resignation or non-qualifying change in status and that supply and equipment requests will not be processed within 30 days of resignation or non-qualifying change. Expenditures prior to resignation or change will only procure adequate material to cover anticipated needs prior to the researcher's departure. Stockpiling of supplies will not be permitted.

Reference Appendix C for procedures regarding Transfer of Funds.

## **PROCESSING BILLS, PURCHASE ORDERS AND PAYMENT REQUESTS**

Reference Appendix D for procedures regarding Processing Bills, Purchase Orders and Payment Requests.

## **PAYROLL PROCESSING**

Timecards are entered onto WorkForceNow, a platform operated by ADP, by the employee on a bi-weekly basis on the Monday following the end of a pay period. The Program Specialist (PS) and Clinical Research Coordinator Manager (CRCM) reviews and approves employee timecards for which they have a supervisory role, including Clinical Research Coordinators, Regulatory Team, and Research Assistants. Employees such as the CRCM, PS, Accounting Support, and individuals employed with NFFRE under Intergovernmental Personnel Agreements (IPAs) will have their timecards reviewed and approved by the Executive Director.

Payroll is processed within ADP WorkForceNow by 2 p.m. on Tuesdays following the end of a pay period. It is the responsibility of the PS and Executive Director to review the Payroll Register for accuracy prior to completing a payroll cycle. Direct deposits and live checks are available on Fridays following the end of a pay period.

Requests for individual early or late payroll processing are considered by the ED, CRCM, and PS on a case-by-case basis.

Reference Appendix E for procedures regarding Payroll Processing.

## **SUPPORT FOR MEETINGS**

Meetings, conferences, workshops, seminars, grand rounds, town halls, symposia, and other similar meetings are accepted features of conducting research and education. Additionally, certain events, such as retreats and board meetings, as well as fundraising and public relations, are necessary for the conduct of business. Incidental to the business purpose of such meetings, it may be appropriate to serve meals or refreshments.

Various regulations, the federal ethics standards and the statute that authorizes NFFRE influence whether expenditures related to such events are appropriate for NFFRE support. Consequently, in order to be considered for NFFRE support by direct payment or reimbursement, NFFRE has established the following policy.

1. In order to be eligible for NFFRE support, a meeting must have a documented research, education or NFFRE business purpose. NFFRE will not support “entertainment” expenses such as social activities, parties, ceremonial occasions or those that provide amusement.
  - For a **research related meeting**: A request for NFFRE support must include an explicit statement about the research rationale for the event; that is, its research related purpose and how it will further VA research. Accompanying documentation should include the program, agenda, or topic of discussion and a roster of attendees. When appropriate, the request should tie the meeting to an approved research project.
  - For an **educational program not related to research**: The education activity itself must first be approved by the VAMC Education Committee. Documentation should include an explicit statement of the purpose and how the program will further the VAMC’s and/or VA’s education and training mission, the agenda, program, or topic of discussion, and a roster of attendees.
  - For **other NFFRE business events**: A request must include an explicit statement of how the meeting will further NFFRE’s ability to facilitate research and education. Appropriate events include, but are not limited to, VA Research Week activities, retreats and board, annual membership, and investigator meetings, as well as fundraising and public relations. Documentation should include the purpose, agenda, program, or topic of discussion and a roster of attendees.
2. The types of meetings that may be eligible for NFFRE support are too numerous to list and the characteristics of appropriate meetings may vary. However, factors that NFFRE will consider when evaluating a meeting for support include:
  - Whether at least one speaker makes a research presentation or presents educational instruction.
  - Whether there is a non-VAMC speaker and/or non-VAMC personnel are among the expected attendees.
  - The frequency of similar meetings that may involve the same personnel. Irregularly scheduled meetings and/or those that occur no more than monthly may be eligible for support; weekly meetings generally will not.
  - Whether support is requested for routine VAMC staff, committee or department meetings. Generally, NFFRE will not support meal expenses for such meetings.
  - Whether the meeting involves at least one individual who is being recruited to facilitate or conduct research or education at the VAMC.
  - Whether the meeting lasts more than two hours or extends through a normal mealtime.

Regardless of the type of meeting, the documentation required in #1 above is a prerequisite for NFFRE support.

3. Requests for NFFRE support will be reviewed and approved by the ED. NFFRE will provide direct payment or reimbursement for reasonable meeting costs based on submission of original, itemized receipts. Charge card receipts will not be accepted. In the event of disagreement, the request will be referred to the President of the board of directors and then the full board if necessary.
4. NFFRE encourages meeting organizers to obtain pre-approval of NFFRE support for meetings. Such approval is not mandatory, but events lacking pre-approval may be denied support or may receive only partial support.

### **MISCELLANEOUS REIMBURSEMENTS**

Research activities occur in a dynamic environment and projection of future needs may not always be possible. Consequently, investigators or their staff may purchase relevant and necessary items and request after-the-fact reimbursement. Every effort should be made by the researcher to use purchase orders when feasible or obtain pre-authorization from the ED for the expenditure. Failure to do so may result in denial of request for reimbursement. All requests for reimbursement must contain adequate documentation justifying the after-the-fact reimbursement and contain a valid sales receipt. An example of an acceptable non-use of a purchase order would be taking advantage of meeting discounts offered for on-site purchase of publications. All miscellaneous reimbursement requests should be submitted to the ED for processing and payment in a timely manner. Investigators are responsible for ensuring the appropriateness of using this mechanism prior to obtaining goods and services. Insufficient or inadequate documentation and justification of requests submitted will result in non-payment. NFFRE reserves the right to deny payment of any submitted reimbursement request that is more than 60 days old.

### **HONORARIA AND TRAVEL REIMBURSEMENT TO GUEST LECTURERS**

Since collaboration and exchange of information is crucial to a productive research environment, members may request reasonable payment to guest lecturers. Such events must have prior approval from the Associate Chief of Staff for Education. Such requests must include the lecturer's name, address, social security number and description of services provided. Requests submitted without this information will be returned to the participant unprocessed. As required by Internal Revenue Service regulations, all payments of \$600 or more made to one individual during any calendar year will result in a Form 1099 being issued. Investigators may also request that actual documented travel expenses be reimbursed to collaborating honoraria individuals. Investigators shall ensure that all such requests are pre-authorized by the ED utilizing the NFFRE Travel Reimbursement form. The request must indicate which expenses are being reimbursed, with original receipts attached, and must indicate the payee's name and where the check should be mailed. Requests submitted without this information will be returned to the participant unprocessed.

### **RESEARCH SUBJECT REIMBURSEMENTS**

All requests for such reimbursements must be submitted on the NFFRE subject reimbursement form. Clinical Research Coordinators are responsible for ensuring that all subject payments have been approved by the Institutional Review Board and the R&D Committee and must submit copies of required approvals to the ED before any subject reimbursement payments will be authorized. Requests submitted without the required information or proof of approvals will be returned to the participant unprocessed. As required by Internal Revenue Service regulations, all payments of \$600 or more made to one individual during any calendar year will result in a Form 1099 being issued.

## **ACCOUNTING**

NFFRE will maintain its financial records on the accrual method of accounting. Under this method, revenues are recognized when earned, and expenses are recognized when the obligation is incurred. NFFRE's fiscal year runs from October 1 through September 30.

NFFRE will utilize adequate accounting software, chart of accounts, and sufficient processes and procedures to ensure accurate reporting on IRS Form 990, financial statements, annual report to VA, annual expenditure reports by investigator/project to VA Research Service (RDIS), other reports as needed and routine account detail and summary to investigators. To ensure protection of NFFRE accounting records, the file backup feature of the accounting software will be used each and every time the software is exited. The feature saves the entire file to a folder on the T: drive on the NF/SG server.

NFFRE will utilize project accounting processes and procedures to maintain multiple accounts, each representing an active project. Funds for an active project are unrestricted to that project. When the work of an active project is finalized and the project closes (through the Institutional Review Board and VA as appropriate), any residual funds will be moved to an unrestricted board designated account, if permitted by the sponsor/donor of the funds.

Reference Appendix F for procedures regarding Accounting.

## **FINANCIAL REPORTS AND RECORDS**

Foundation financial records will be reviewed at the end of each month. This end-of-month activity results in generating monthly cash receipts and cash disbursements ledgers, individual summary reports by account for cash receipts and cash disbursements, and individual account balance reports. Cash receipts and cash disbursements ledgers are available electronically as part of the permanent record file. Overdrawn project accounts will be reported to the board quarterly and appropriate action will be taken to resolve them.

Financial statements will be given to each board member on a timely basis with explanations of large variances from budget and from the previous year.

A short narrative will be provided to the board describing NFFRE's current financial position and results of operations at each scheduled meeting.

Reference Appendices G, H, and I for procedures regarding month end reports.

## **PROCUREMENT POLICY**

Supplies and expenditures in support of research activities such as chemicals, animal, laboratory supplies, etc. may be requested by the Principal Investigator by submitting the appropriate paperwork to NFFRE. This includes request for check or request for payment via credit card.

### **Background:**

When requesting payment for an order, documentation must include:

- Date of request

- Project name (specify a study)
- Investigator signature (certifies the purchase as necessary to the project)
- Research justification

Individuals will be reimbursed for expenditures made for small items or supplies necessary to a particular project, with prior approval by the Executive Director. **All original receipts must be attached to the reimbursement request.**

A credit card may be issued to the Executive Director to be used for legitimate NFFRE business. This includes, but is not limited to, travel and project-related purchases.

### **Guidelines:**

All purchase requests must be submitted on NFFRE forms, not VA forms. The Program Specialist will review paperwork to ensure all items are filled in properly. The Executive Director approves all purchases. The Program Specialist or Executive Director orders all items.

For purchases, the Principal Investigator reviews orders upon receipt and provides the packing slips to the Executive Director as verification of receipt. Payments are made after an original invoice is received if a purchase order is used.

If NFFRE reviews a proposed expenditure and deems it inappropriate, the Principal Investigator may seek review by the Board of Directors for final disposition.

**NOTE:** All disapproved requests will be retained in the NFFRE Research File as evidence of review and disapproval for future audits.

Supplies, equipment, and needed services may be purchased on the open market. Any item over \$5,000 must have at least three (3) bids unless sole source justification can be provided. All equipment items purchased for permanent, long-term use, valued over \$5,000 are to be capitalized.

### **RECONCILIATION OF BANK STATEMENTS**

A complete set of NFFRE financial records is assembled at the end of each fiscal year. This electronic and/or permanent financial record includes monthly cash receipts ledgers, summary of funds received by investigator, summary of funds received by donor, monthly cash receipts ledgers, consolidated cash disbursements by account listing all expenditures from the year, and a consolidated investigator balance report and reconciliation statement listing all transactions from the year ended.

Bank reconciliations will be signed and dated by both preparer (outside accountant) and approver (ED). Bank statements are routinely being reviewed and approved by ED.

Reference Appendix H for procedures regarding Reconciliation of Bank Statements.

### **BANKING**

NFFRE checking is handled via a FDIC-insured financial institution. Board review and approval is required before any financial institution may be engaged by the ED. Board actions concerning designation of a financial institution will be clearly documented in subsequent meeting minutes. Copies of all NFFRE banking delegations will be maintained on file by the ED.

The ED is responsible for monitoring the balance of funds available in these accounts to ensure maximum FDIC protection.

Petty cash accounts will not be used by NFFRE.

## **INVESTMENTS**

All investments held by NFFRE must be protected by direct FDIC coverage or backed by the full faith and credit of the Federal government. Board review and approval is required before any financial institution may be engaged by the ED. Board actions concerning designation of a financial institution will be clearly documented in subsequent meeting minutes. Currently, Merrill Lynch provides investment services that offer options guaranteeing all investments are insured by FDIC. Funds are placed in treasury notes or bills, and/or certificates of deposit (CD) in appropriate dollar-amount blocks. The amount provides full FDIC protection for the principal and interest earnings. Some funds will be maintained in an FDIC-insured cash account. This account will provide a safety net to avoid early liquidation of other investments and possible penalties during times of reduced cash flow. The funds would be available for use when monthly cash disbursements exceed cash receipts. In accordance with NFFRE By-Laws, only the ED, the President of the Board of Directors or the Medical Center Director may authorize transactions for these accounts.

## **AUDITS/IRS FORM 990 PREPARATION/ANNUAL REPORT TO VACO**

VA regulations require that (1) either a yearly or triennial audit of all NFFRE finances, depending on revenue, be performed by an independent accounting firm approved by the board of directors and (2) an annual report be made to the VA Nonprofit Office. Copies of the annual report to the VA Nonprofit Office will be supplied to NF/SG Chief Financial Officer. In addition, Internal Revenue Service (IRS) regulations require yearly submission of Form 990 for all non-profit organizations. The ED will obtain a letter of engagement from the independent auditor. Subsequent minutes will document specific Board action concerning proposed audit and Form 990 preparation. The ED will ensure that NFFRE records required to complete these tasks are assembled and made available to the auditors for the year just ended and scheduled for audit.

## **RECORD RETENTION**

It is the policy of NFFRE to retain corporate records as necessary to meet IRS requirements, federal and state laws and to destroy them if or when appropriate.

The destruction of records must be approved via Records Destruction Request Form. Once the records have been destroyed, a copy of the Records Destruction Request Form will be included in NFFRE's records destruction log.

Upon receiving notification of any investigation, all records destruction, scheduled or otherwise, will be suspended pending resolution of the investigation.

## **PROCUREMENT**

Established procedures must be followed for the procurement of supplies, expendable property, real property, and services required to meet NFFRE's research mission as outlined in the organization's *MISSION STATEMENT*. NFFRE is a private, non-profit research organization incorporated in the State of Florida. With the exception of the DVA Secretary's regulations and

certain ethics laws and regulations, those federal laws, standards and regulations governing Federal agencies, such as the Federal Acquisition Regulations (FAR) and Office of Management and Budget (OMB) circulars, are not applicable to NFFRE procurement guidelines as established in this policy until expenditures of Federal funds exceed \$500,000 per year. The President of the Board of Directors, ED, and Medical Center Director are the only NFFRE officials authorized to make commitments of NFFRE funds under this policy. Appropriate participant expenditures may include, but are not limited to, laboratory supplies and equipment, subject reimbursement fees, books, journal subscriptions, honoraria, consulting fees, office supplies and equipment, and outside services provided by non-profit or for-profit individuals or companies. All expenditures must demonstrate clear prima facie research or education relevance (e.g., glassware, radioisotopes, serum, chemicals, honoraria) or provide additional written documentation at the discretion of the ED.

No employee, officer, director, or agent of NFFRE shall participate in the selection, award, or administration of a NFFRE procurement if a real or apparent conflict-of-interest would be involved. Such a conflict would arise when the employee, officer, director, or agent, any participant or his or her immediate family, his or her partner, or an organization which employs or is about to employ any of the parties indicated herein, has a financial or other interest in the firm selected for a procurement award. The directors, officers, employees, and agents or the recipient shall neither solicit nor accept gratuities, favors, or anything of monetary value from contractors, or parties to sub agreements other than items of nominal value or routine meals in the normal course of business.

Sole source awards (purchases) are permitted but must be reviewed and approved by the President, board of directors, or the ED on a case-by-case basis. Sole source awards will only be considered when it is determined that the project completion hinges on the quality, history, skills or expertise offered by the sole source provider in question or is required by Federal law related to grants administration.

Procurements will only be made with responsible sources who possess the potential ability, as determined by NFFRE, to perform successfully under the terms and conditions of the proposed procurement. Consideration shall be given to such matters as contractor integrity, record of past performance, financial and technical resources, or accessibility to other necessary resources to perform the work in question. Investigators are responsible for determining and recommending the most appropriate and beneficial source for their submitted procurement requests. No-bid lists, pre-qualified bidders, mandatory sources, and advertised announcements seeking bids or proposals will not be part of NFFRE's procurement policy until expenditures of federal funds exceed \$500,000 per year. Due to the unique relationship that exists between NFFRE and NF/SG, many companies will extend GSA price discounts to purchases placed by NFFRE. While GSA discount availability is at the discretion of the supplier, acceptance will be at the sole discretion of NFFRE based on a cost/benefit/availability analysis.

### **REIMBURSING NF/SG FOR CLINICAL SERVICES THAT ARE PURELY RESEARCH**

To ensure that NF/SG is properly reimbursed at an appropriate rate for costs incurred in the performance of a research study that is considered above and beyond normal patient care, the ED, with the assistance of investigator, will develop a budget utilizing a database provided by NF/SG Chief Financial Officer. The database provides costs for this particular facility based on CPT codes. NFFRE will collect the appropriate funds from the study and facilitate their deposition to NF/SG.

## **SUBSCRIPTION AND MEMBERSHIP REQUESTS**

Expenditures for continued education, including scientific books, conference and registration fees, society memberships, etc., specifically relating to a research activity may be requested by submitting the appropriate paperwork to NFFRE. Subscriptions or professional association dues, with the exclusion of license fees, may be paid from appropriate research or general operating funds upon approval by the ED.).

Organizational memberships cannot be paid for by Foundation funds unless that membership is necessary to receive the organization's journal or publications.

Any incomplete requests will be returned to the participant. Renewals can only be made for one year at a time.

## **PURCHASE ORDERS**

Requests for equipment or supply orders requiring a purchase order must be submitted to the ED and must contain required ordering information (stock number, item description, quantity, unit price, date required). The order must include the vendor name, address, and telephone number. All requests received will be reviewed and approved by the ED prior to orders being placed by ED or administrative staff. All orders are delivered to NFFRE offices. The ED will signify approval on all purchase requests up to \$5,000. Orders over \$5,000 will require additional review and signature of the Secretary/Treasurer.

## **CONTRACTS/GRANTS**

All items required by contract or grant will begin with the appropriate investigator's development of a specific "statement of work" to be completed and an estimated period of agreement. Parties interested in performing the work in question will be required to submit complete written proposals. The proposals must contain a specific plan for completing the work defined in NFFRE's "statement of work" with an appropriate timeline. The proposal must also contain itemized yearly budgets by category (personnel, supplies, equipment, travel, etc.).

Final contract documents awarded by NFFRE will contain at a minimum: (a) Statement of Work, (b) Period of Agreement, (c) Authorized Budget, (d) Project Officer/Key Personnel Identification, (e) Progress Report Schedule, (f) Billing Procedures, (g) Termination Clause, and (h) Equipment Ownership.

All contracts and grants must have prior legal review before being executed. All contracts must be signed by the ED.

Clinical trials must be contracted with Cooperative Research and Development Agreements when appropriate. They require Regional Counsel review and will be signed by the Medical Center Director and the ED.

## **EQUIPMENT**

Physical assets acquired with unit costs in excess of \$5,000.00 and will be used for more than one year are capitalized as fixed assets on the financial statements. Items with unit costs below this threshold shall be expensed in the year purchased. If the equipment will be used for one study in one year, it will be expensed.

## **SURPLUS EQUIPMENT**

The board of directors has determined all surplus equipment will be made available first to the NF/SG. Functional surplus equipment turned down by the NF/SG can be made available to other NFFRE participating Investigators. All items of equipment accepted for transfer will be acknowledged in writing by the receiving investigator. Appropriate documentation will be maintained by the investigator or staff that procured this equipment.

## **TRANSFER OF EQUIPMENT**

Investigators who have a change in NF/SG employment status or one that affects their WOC appointment no longer meet NFFRE investigator requirement. As a result, any equipment inventory will be handled according to this policy which stipulates equipment may only be transferred to another 501(c)(3) organization (Internal Revenue Service regulation), if (a) the program is continuing at the time of the investigator's resignation, and (b) there is no current or projected need for the equipment at the NF/SG. Equipment transfers meeting these requirements must be documented in writing by the ED. Minimum documentation will include a letter from NFFRE's ED offering the equipment for transfer, a letter from the receiving organization's Director accepting the equipment, and proof of the receiving organization's 501(c)(3) status.

## **PERSONNEL**

NFFRE may employ full, part-time and PRN employees as required to carry out the investigator's research activities. The length of employment for such individuals shall be indefinite, with no time commitments made or implied. The hiring, termination, assignment of duties, and the determination of reasonable salary levels shall be upon the recommendation of the ED. Specific tours of duty will be set by the direct supervisor. Full-time shall mean 40 hours per week.

Full and part-time NF/SG employees may be hired by NFFRE (providing no DVA regulation prohibits or restricts potential outside employment) to carry out the research or education activities of the Investigators. In the case of full-time NF/SG employees, the services provided must be above and beyond and entirely different from the employee's normal NF/SG duties and responsibilities, such determination to be made by the ED with input from the investigator requesting to hire the NF/SG employee. NFFRE timecards for NF/SG employees must indicate the time their hours were worked. This provides NFFRE oversight to help ensure NF/SG employees are not knowingly being compensated for NF/SG-paid hours.

## **EMPLOYEE HIRING PROCEDURE**

Investigators may not request hiring authorization unless at least six months of salary support and fringe benefits (as applicable) are available in their account or a guaranteed salary is budgeted. Requests for authorization to hire which are submitted before adequate funds are available or guaranteed will be returned unprocessed to the investigator. When these requirements are met, a memorandum identifying the duties, responsibilities, qualifications, assumed term of the project, and proposed salary (yearly or hourly) must be submitted to the ED. Once this memorandum and a detailed position description have been reviewed and approved by the ED, NFFRE will make an offer of employment. It is understood, however, that the offer of employment is not to imply employment of a hiree for the entire term of such a project. Investigators are required to review and discuss with prospective employees NFFRE Employment Application Disclaimer, the Immigration and Naturalization Service (INS) I-9 form, and the annual certification of Federal Standards of Ethical Conduct and Related

Responsibilities of Employees. Completion of all three forms is mandatory for NFFRE employment. Investigators should be aware that no salary payments will be authorized for any individual prior to review and approval date by the ED. As of March 26, 1998, the board of directors has made the determination that no salaries will be paid to Investigators (M.D., Ph.D.,) using NFFRE funds.

## **WITHOUT-COMPENSATION (WOC) APPOINTMENT AND NEW EMPLOYEE ORIENTATION**

Since all NFFRE employees perform regular duties at NF/SG, they must have official NF/SG authorization to be on the premises. Accordingly, all NFFRE employees will be issued WOC appointments from NF/SG. This appointment provides the mechanism for NFFRE employees to obtain a NF/SG ID or PIV badge. After Investigators have requested and received approval to hire an employee, all necessary paperwork and training to obtain a WOC appointment letter from VA Research Service is required. Once the WOC appointment has been obtained the new employee will complete the NFFRE application package to be approved by the ED. The ED will utilize the framework of documentation and training required throughout the WOC process to begin new employee orientation. Internal controls training will be provided to directors, officers and employees with decision-making authority within 90 days of hire or affiliation. The orientation will continue as needed throughout the early days of the employee's service. Please refer to the NFFRE Employee Handbook in ADP WorkForce Now.

## **WOC TRAINING REQUIREMENTS**

While the WOC letter provides authorization for NFFRE employees to be in the NF/SG facility and provides certain benefits, it also imposes mandatory training requirements by the NF/SG. Since NFFRE employees are located in a NF/SG facility, accrediting organizations require that these employees receive the same mandatory yearly training required for regular NF/SG employees. Accordingly, supervisors are responsible for ensuring their NFFRE employees attend all required training as a condition of their continued WOC status at the NF/SG. Failure to meet mandatory NF/SG training requirements such as safety, animal use, radiation safety, etc., could result in termination of an employee's WOC status. This would result in their immediate termination from NFFRE.

## **STANDARDS OF ETHICS CERTIFICATION**

As outlined in the *OVERSIGHT AUTHORITY* section, the DVA has mandated additional regulations for DVA non-profit research corporations. A specific requirement is the mandatory yearly certification by all NFFRE directors, officers, and employees of compliance with the Standards of Ethical Conduct and Related Responsibilities of Employees. A form certifies that the signatory is aware of, and has not violated, Federal conflict of interest regulations.

## **EMPLOYMENT APPLICATION DISCLAIMER**

Due to the unpredictable nature of project-based research funding, length of employment for NFFRE employees shall be unspecified, with no time commitments made or implied. Accordingly, all applicants for employment must complete NFFRE's Employment Application Disclaimer. The purpose of the Disclaimer is to inform the applicant their employment will be "at will", is not for any specific duration, and may be terminated at any time without advance notice.

## **MEDIATION**

Employees agree to mediate workplace disputes in a good faith attempt to resolve serious conflicts arising as a result of their employment. The employer and the employee shall share costs of mediation sessions equally. The mediator(s) shall be agreed upon by the employee and the employer prior to the mediation session. If the parties cannot agree to the choice of mediators, the Board of Directors of NFFRE shall select an impartial mediator from the nearest VA facility.

## **WHISTLEBLOWER POLICY**

**General.** NPC Code of Ethics and Conduct ("Code") requires directors, officers and employees to observe high standards of business and personal ethics in the conduct of their duties. As employees and representatives of the NPC, we must practice honesty and integrity in fulfilling our responsibilities and comply with all applicable laws and regulations.

**Reporting Responsibility.** It is the responsibility of all directors, officers and employees to comply with the Code and to report violations or suspected violations in accordance with this Whistleblower Policy.

**No Retaliation.** No director, officer or employee who in good faith reports a violation of the Code shall suffer harassment, retaliation or adverse employment consequence. An employee who retaliates against someone who has reported a violation in good faith is subject to discipline up to and including termination of employment. This Whistleblower Policy is intended to encourage and enable employees and others to raise serious concerns within the NPC prior to seeking resolution outside the NPC.

**Reporting Violations.** The Code addresses the NPC's open-door policy and suggests that employees share their questions, concerns, suggestions or complaints with someone who can address them properly. In most cases, an employee's supervisor is in the best position to address an area of concern. However, if you are not comfortable speaking with your supervisor or you are not satisfied with your supervisor's response, you are encouraged to speak with a board member or anyone in management whom you are comfortable in approaching. Supervisors and managers are required to report suspected violations of the Code of Conduct to and NFFRE Board of Directors' Treasurer, who has specific and exclusive responsibility to investigate all reported violations. For suspected fraud, or when you are not satisfied or are uncomfortable with following the NPC's open-door policy, individuals should contact the designee directly.

**Reporting Individual.** The Chief of Staff or Acting Chief of Staff is responsible for investigating and resolving all reported complaints and allegations concerning violations of the Code and, at his or her discretion, shall advise the ED and/or the audit committee. Designee has direct access to the audit committee of the board of directors and is required to report to the audit committee at least annually on compliance activity. Designee is the chair of the audit committee.

**Accounting and Auditing Matters.** The board of directors shall address all reported concerns or complaints regarding corporate accounting practices, internal controls or auditing. The Board treasurer shall immediately notify the audit committee of any such complaint and work with the committee until the matter is resolved.

**Acting in Good Faith.** Anyone filing a complaint concerning a violation or suspected violation of the Code must be acting in good faith and have reasonable grounds for believing the information disclosed indicates a violation of the Code. Any allegations that prove not to be substantiated and

which prove to have been made maliciously or knowingly to be false will be viewed as a serious disciplinary offense.

**Confidentiality.** Violations or suspected violations may be submitted on a confidential basis by the complainant or may be submitted anonymously. Reports of violations or suspected violations will be kept confidential to the extent possible, consistent with the need to conduct an adequate investigation.

**Handling of Reported Violations.** The Chief of Staff or Acting Chief of Staff and/or the Executive Director will notify the sender and acknowledge receipt of the reported violation or suspected violation within five business days. All reports will be promptly investigated, and appropriate corrective action will be taken if warranted by the investigation.

## **IMMIGRATION AND NATURALIZATION SERVICE FORM I-9**

The United States Congress passed legislation requiring the Immigration and Naturalization Service (INS) to ensure that any individual working in the US is legally entitled to do so. As a result, the INS require all US employers to have prospective employees complete an I-9 form before being hired. This form mandates that prospective employees must provide several types of formal identification (as prescribed by INS regulation) to potential employers to establish their right to work in the United States. Considerable fines may be imposed by the INS against employers failing to complete this documentation for all employees on their payroll. Accordingly, no individual will be employed by NFFRE prior to completing their INS I-9 form.

## **DRUG-FREE WORKPLACE**

NFFRE certifies it will provide a drug-free workplace. The unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the NF/SG. As a condition of employment, every NFFRE employee will abide by the terms of the preceding statement and will notify NFFRE ED of any criminal drug statute conviction for a violation occurring in the workplace no later than five (5) days after such conviction.

Drug usage by NFFRE employees could result in personal injury or loss of life or in the loss of patient's lives or patient injury. NFFRE has an obligation to take the necessary steps to eliminate illegal drug use from the workplace.

Since the NF/SG is the site for performance of NFFRE work, employees come under the auspices of some, but not all, aspects of the DVA Drug-Free Workplace Program. The DVA Employee's Guide "*Achieving a Drug-Free Workplace*" is available for review in NFFRE Office. Specifically, NFFRE employees may be subject to pre-employment drug testing, reasonable suspicion testing, and accident or unsafe practice testing. NFFRE is not obligated to provide its employees drug counseling, rehabilitation, or any other employee assistance program benefit. The Board of Directors will determine penalties that may be imposed upon NFFRE employees for drug-abuse violations occurring in the workplace up to and including termination. Specific questions concerning this policy should be directed to NFFRE Office.

## **TRAVEL POLICY**

NFFRE was formed to further medical science by promoting research and education. Expenditures related to research and educational activities are also appropriate and necessary to accomplish NFFRE's mission. Accordingly, certain funds donated to and accepted by NFFRE may be used to reimburse travel expenses associated with furthering research and education

relevant travel activities. Acceptable are meetings of clinical specialty societies, research societies, national and international general clinical and research groups and organizations who's recognized or stated primary goals are to further medical knowledge, research, public health and/or education. However, the proposed travel must have demonstrable research relevance. Approval of proposed NFFRE travel funding requests will be the responsibility of the NFFRE ED. If needed, the final authority for interpretation resides with the President, Board of Directors. It is the responsibility of the traveler to submit adequate material to justify the primary research or education purpose. NFFRE has been established to support NF/SG research. Accordingly, the Board of Directors has authorized the denial of travel support to Investigators failing to appropriately acknowledge their institutional affiliation in publications or at meeting presentations.

All expenses must be pre-approved by the ED and paid by the traveler in advance and will be promptly reimbursed upon completion of approved travel except in cases where such expenditures would create a financial hardship for the traveler, e.g., a Clinical Research Coordinator traveling to an investigator's meeting to receive training for the conduct of a clinical trial. Large registration fees (over \$300) may be paid in advance directly to the conference organization with authorization by the ED.

NF/SG employees traveling on NFFRE funds must be on appropriate travel status or authorized absence to receive reimbursement for their travel expenses. No support will be provided when or if the traveler is on annual leave. This is necessary to monitor and comply with conflict of interest issues. In all cases, travel reimbursements will only be made if the time, place and business purpose of the travel is substantiated by adequate records or other evidence. Travelers are permitted the federal locality per diem rate for meals and incidental expenses. For partial days of travel, the meals and incidental per diem rate must be prorated to 75% of the per diem rate. A full day of travel is considered to be from 12:01 a.m. to 12:00 midnight. Receipts are required for hotel, ground transportation, airfare and conference fees. A "reasonable" amount for hotel costs, as determined by the meeting site and prevailing hotel rates, will also be covered. Travelers must substantiate their room rate with program material detailing prevailing rates. Maximum transportation reimbursement shall be limited to the equivalent direct coach fare by airplane or train. Reimbursement will be made at the prevailing Federal mileage reimbursement rate plus applicable tolls, but in no case will exceed the coach air fare to the location in question. Mileage will be documented via travel website (e.g., MapQuest). Ground transportation costs are generally limited to reimbursement for costs to and from the city of departure airport/train station (plus parking); airport/train station to hotel, and hotel to airport/train station. A receipt is required for parking charges. In addition, a receipt is required for all cabs. Once the traveler has arrived at the hotel, taxi cabs will not ordinarily be reimbursed (i.e., go to dinner, etc.). Because meeting hotels are generally within walking distance or provide free shuttle service to the conference, this type of cab fare over \$25, will require a separate justification attached to the traveler's reimbursement voucher. These taxi expenditures will be reviewed and approved by the ED on a case-by-case basis. In certain cities use of a rental car may be authorized, but only if approved in advance by the ED.

When travel costs are supported by joint sponsors (NFFRE and VA or University), NFFRE will cover only items not designated for any payment by the joint sponsor. NFFRE will not pay for partial costs of any charge not fully covered by the joint sponsor (i.e., ½ of airfare or ½ per diem).

Foreign travel will only be reimbursed for the dates of the meeting submitted on the travel request. VA regulations require that annual leave be taken when traveling abroad.

Reference Appendix I for procedures regarding Travel.

## **PROCEDURES FOR OBTAINING REIMBURSEMENT FOR TRAVEL EXPENSES**

All individuals requesting travel support must complete NFFRE Travel Authorization Request. This form incorporates VA and IRS requirements. Specifically, all requests for travel must justify NF/SG program relevance for the Member or other authorized individual requesting travel funds from NFFRE. Approval of all travel requests is dependent on an appropriate program relevance justification. In addition, travelers making presentations must include a copy of their invitation or acceptance letter or other documentation of their presentation.

NF/SG employees requesting NFFRE travel support must also complete VA Form 0893 and obtain their supervisor's signature on the form. A DVA Leave Approval Form must also be provided. If NFFRE travel support is requested in conjunction with NF/SG authorized travel, a copy of the DVA Travel Orders may be used in lieu of the DVA Leave Request.

Travelers will submit the completed form(s) in advance to NFFRE ED for approval. A copy of the ED-approved form will be provided to the traveler and the original form retained in the pending travel file until reimbursement is requested. The ED will arrange Regional Counsel Review of VA Form 0893. This must be done prior to the travel.

Reimbursement for completed travel should be requested promptly. No reimbursements will be made to any traveler until all required paperwork has been completed and approved. Travelers should complete and submit NFFRE Travel Reimbursement Form to the ED for processing, ensuring that all required ORIGINAL receipts are attached. Once received, the ED will audit the request, ensure that appropriate receipts have been provided, and verify the total amount of the reimbursement requested. A check will be issued by the ED to the traveler. A set of all paperwork will be maintained in NFFRE accounting records. Payments made to the ED for travel/other significant reimbursements will be approved (signed & dated) by a board member.

## Clinical Trial Center Procedures

### QuickBooks Setup

Every entry into QB must have a Customer, Job & Class assigned.

#### Customer

- CRADA's, Grants, Subawards = Principal Investigator
- IPA = Principal Investigator
- MOU = Sponsor of MOU
- Administrative = NFFRE Administrative
- Clinical Trial Center = NFFRE Clinical Trial Center
- Education
- Fundraising

#### Job

- CRADA's = Project Short Name, IRB or Protocol Number, Sponsor
- IPA = Project Short Name, IRB or Protocol Number, Last Name, First Initial (IPA)
- MOU = Project Short Name, IRB or Protocol Number (if applicable), Last Name, First Initial (if applicable) (MOU)
- Federal & Non-Federal Grants = Project Short Name, IRB or Protocol Number, Sponsor
- Federal & Non-Federal Grant Subaward = Passthrough Entity, Project Title, IRB or Protocol Number, Sponsor
- Administrative = Administrative Job
- Clinical Trial Center = Clinical Trial Center Job

#### Class

- Balance Sheet – all Balance Sheet accounts
- Clinical Trial Center – CRADA's and CTC revenue & expenses (includes CTC Assessment Revenue)
- Administrative – Administrative revenue & expenses (includes Administrative Assessment Revenue, Federal Grant Administrative Assessment (IDC), Non-Federal Grant Administrative Assessment Revenue (IDC))
- IPA – IPA related revenue & expenses
- Grant - Federal – Federal grant revenue & expenses
- Grant – Non-Federal – Non-federal grant revenue & expenses
- MOU – MOU revenue & expenses
- Subaward – Grant-Federal or Grant-Non-Federal
- Education – Federal - Education related revenue & expenses
- Education – Non-Federal - Education related revenue & expenses
- Fundraising – Charitable contribution revenue & fundraising expenses
- Pilot - NFFRE funded Pilot award related revenue & expenses
- Assessment Expense - used for CTC Assessment Expense or Administrative Assessment Expense (the offset accounts for CTC Assessment Revenue and Administrative Assessment Revenue)

**Examples:**

CRADA: Panna, Mark: SMART, 201700590, Boston Scientific, Clinical Trial Center

Federal Grant Subaward: Levy, Charles: OSRI, Upper Limb Amputation, 16-20, DoD, Grant – Federal

Non-Federal Grant Subaward: Yarrow, Joshua: KSU, Tumor Oxy, RSG-14-150-01-CCE, American Cancer Society, Grant - Non-Federal

MOU: VACREF: CSPCO, Falzone, M. (MOU), MOU

IPA: Segal, Mark: EPO, 201700031, Stinson, S. (IPA), IPA

Administrative: NFFRE Administrative: Administrative Job, Administrative

CTC: NFFRE Clinical Trial Center: Clinical Trial Center Job, Clinical Trial Center

## **Invoicing Procedure**

**IPA**

1. IPA's should be invoiced according the IPA agreement, monthly or quarterly, but at a minimum quarterly.
2. Either invoice a fixed amount per the IPA agreement, or run the appropriate Customer/Job P & L for the time period covered.
3. Use IPA Invoice Template
4. Select appropriate Customer:Job
5. Select IPA Class
6. Select IPA Item ID
7. In Description, enter [Last Name], [First Name] & For Period Covering [Date Range]
8. Account Number should be 4610 – IPA Revenue
9. Select Class – IPA
10. When line items are complete, save invoice and send to Sponsor through QuickBooks. Then save the invoice as PDF to appropriate customer/job folder

**MOU**

1. MOU's should be invoiced according the MOU agreement, monthly or quarterly, but at a minimum quarterly.
2. Use MOU Invoice Template
3. Select appropriate Customer:Job
4. Select MOU Class
5. Select MOU Service Item ID
6. In Description, Enter Last Name, First Name & period of time to invoice
7. Account Number should be 4620 – MOU Revenue
8. Select MOU IDC item id, and enter the appropriate percentage where the "X%" is

9. Enter the amount that is the appropriate % times the invoice value
10. When line items are complete, save invoice and send to Sponsor through QuickBooks. Then save the invoice as PDF to appropriate customer/job folder
11. Select List, Memorized Transaction List & select Admin MOU Invoice JE
  - a. Enter the date of the invoice
  - b. Enter the invoice # in the following format at Entry No. "INV1234"
  - c. Enter the amount of MOU Admin assessment revenue in the Debit column on Line 1, and in the credit column on Line 2
  - d. Enter the study customer/job name in the "Name" column on Line 1
  - e. Enter the invoice # in the Memo field & copy it down to all line items
  - f. Save & Close the journal entry

### **CRADA (Milestone – no invoice is provided to Sponsor)**

1. CRADA's should be invoiced mid-month & at month-end based on the activity in QuickBase (based on milestones met for the period)
2. Log into HASPOA QuickBase site to obtain billing data related to completed visits
  - a. Prepare a Completed Visits spreadsheet by Clicking on "Completed Visits" towards the top of the screen, then "Reports & Charts", then "Choose start and end dates excluding invoiced items" (it is recommended that the beginning date be 1/1/XX through the date for which you are invoicing so that items which are entered by coordinators after period close are captured in the later period);
  - b. The Completed Visits report should be reflected in order by study name so that billing items are grouped into studies with the totals reflected – this will allow you to confirm that the invoice as prepared in QuickBooks agrees with the billable CRF items reflected in QuickBase; and
  - c. Save the report as a combined report (not as individual items) in the month-end folder
3. In QuickBooks, use the CRADA Invoice Template to prepare the internal memorandum invoice:
  - a. Each Customer:Job should be reflected on a separate invoice
  - b. Select appropriate Customer:Job
  - c. Select the Clinical Trial Center class
  - d. Select the appropriate item id: CRADA Service item, Pharmacy, Supplies, Participant Reimb etc, and enter the appropriate description and amount to be charged based on the QuickBase report
  - e. For each line item, enter the Class as Clinical Trial Center
4. Once milestones have been entered, add the following line items:
  - a. Select CTC Expense Assess Item ID and CLINICAL TRIAL CENTER class
  - g. Enter amount as a negative at 70% of total invoice value
  - h. Select CTC Income Assess item ID and CLINICAL TRIAL CENTER class
  - i. Enter amount as positive at 70% of total invoice value
  - j. Select Admin Expense Assess item ID and CLINICAL TRIAL CENTER class
  - k. Enter amount as a negative at 23% of total invoice value
  - l. Select Admin Income Assess item ID and CLINICAL TRIAL CENTER class
  - m. Enter amount as positive at 23% of total invoice value
5. Save invoice as PDF to appropriate customer/job folder
6. Select List, Memorized Transaction List & select Admin CTC Invoice JE
  - n. Enter the date of the invoice

- o. Enter the invoice # in the following format at Entry No. "INV1234"
- p. Enter the amount of CTC assessment revenue (70%) in the Debit column on Line 1, and in the credit column on Line 2
- q. Enter the study customer/job name in the "Name" column on Line 1 & Line 3
- r. Enter the amount of the Admin assessment revenue (23%) in the Debit column on Line 3, and in the credit column on Line 4
- s. Enter the invoice # in the Memo field & copy it down to all line items
- t. Save & Close the journal entry

### **CRADA (Expenses – invoice is provided to Sponsor)**

1. CRADA's should be invoiced mid-month & at month-end based on the activity in QuickBase (based on milestones met for the period); however, the invoice is provided to the Sponsor once per month at month-end
2. Log into HASPOA QuickBase site to obtain billing data related to expenses
  - a. Prepare an Expenses spreadsheet by Clicking on "Expenses" towards the top of the screen, then "Reports & Charts", then "Choose start and end dates excluding invoiced items" (it is recommended that the beginning date be 1/1/XX through the date for which you are invoicing so that items which are entered by coordinators after period close are captured in the later period);
  - b. The Expenses report should be reflected in order by study name so that billing items are grouped into studies with the totals reflected – this will allow you to confirm that the invoice as prepared in QuickBooks agrees with the billable CRF items reflected in QuickBase; and
  - c. Save the report as a combined report (not as individual items) in the month-end folder
3. In QuickBooks, run the P & L By Job for the Customer:Job for the appropriate time frame
  - a. Save the P & L by Job to PDF to the appropriate Customer/Job folder
4. In QuickBooks, use the CRADA Invoice Template to prepare the internal memorandum invoice:
  - a. Each Customer:Job should be reflected on a separate invoice
  - b. Select appropriate Customer:Job
  - c. Select the Clinical Trial Center class
  - d. Select the appropriate item id: CRADA Service item, Pharmacy, Supplies, Participant Reimb etc, and enter the appropriate description and amount to be charged based on the QuickBase report
  - e. For each line item, enter the Class as Clinical Trial Center
  - f. When expense line items are complete, save invoice and send to Sponsor through QuickBooks. Then save the invoice as PDF to appropriate customer/job folder
5. Reopen the invoice in QuickBooks & add the following line items:
  - a. Select CTC Expense Assess Item ID and CLINICAL TRIAL CENTER class
  - u. Enter amount as a negative at 70% of total invoice value
  - v. Select CTC Income Assess item ID and CLINICAL TRIAL CENTER class
  - w. Enter amount as positive at 70% of total invoice value
  - x. Select Admin Expense Assess item ID and CLINICAL TRIAL CENTER class
  - y. Enter amount as a negative at 23% of total invoice value
  - z. Select Admin Income Assess item ID and CLINICAL TRIAL CENTER class
  - aa. Enter amount as positive at 23% of total invoice value
6. Save invoice & Close
7. Select List, Memorized Transaction List & select Admin CTC Invoice JE

- bb. Enter the date of the invoice
- cc. Enter the invoice # in the following format at Entry No. "INV1234"
- dd. Enter the amount of CTC assessment revenue (70%) in the Debit column on Line 1, and in the credit column on Line 2
- ee. Enter the study customer/job name in the "Name" column on Line 1 & Line 3
- ff. Enter the amount of the Admin assessment revenue (23%) in the Debit column on Line 3, and in the credit column on Line 4
- gg. Enter the invoice # in the Memo field & copy it down to all line items
- hh. Save & Close the journal entry

## Research Grant – Federal & Non-Federal

1. Research Grants should be invoiced at month-end based on the activity in QuickBooks compared to QuickBase to ensure that the maximum expense amount allowed is not exceeded.
2. In QuickBooks, run the P & L By Job for the Customer:Job for the appropriate time frame
  - a. Save the P & L by Job to PDF to the appropriate Customer/Job folder
8. Log into HASPOA QuickBase site to obtain billing data related to expenses
  - a. Prepare an Expenses spreadsheet by Clicking on "Expenses" towards the top of the screen, then "Reports & Charts", then "Choose start and end dates excluding invoiced items" (it is recommended that the beginning date be 1/1/XX through the date for which you are invoicing so that items which are entered by coordinators after period close are captured in the later period);
  - b. The Expenses report should be reflected in order by study name so that billing items are grouped into studies with the totals reflected – this will allow you to confirm that the invoice as prepared in QuickBooks agrees with the billable CRF items reflected in QuickBase; and
  - c. Save the report as a combined report (not as individual items) in the month-end folder
4. In QuickBooks, use the Grant Invoice Template to prepare the internal memorandum invoice:
  - a. Select appropriate Customer:Job
  - c. Select the Grant – Federal Grant Class for Federal or Grant – Non-Federal Grant Class if non-Federal
  - d. Select the Grant Federal Service Item id or the Grant Non-Federal Service Item id, and enter the appropriate description and amount to be charged based on the QuickBooks & QuickBase reports
  - e. For each line item, enter the Class as Grant – Federal Grant or Grant – Non-Federal Grant
  - f. When expense line items are complete, select the Federal IDC item id or Non-Federal IDC item id, change the "X%" to the appropriate percentage and calculate the amount to be charged based on the total invoice value times the percentage
  - g. On a blank line, enter the following in the Description column "[Year of the contract], current year [date] current expenses: [\$ amount of current invoice]
  - h. On next blank line, enter the following in the Description column "Cumulative Expenses: [\$ amount of the cumulative running total for that current year]
  - i. On next blank line, enter "I certify that these expenses were incurred by [Subaward #]
  - j. On next blank line, Sign: [name of executive director]
  - k. On next blank line, Sign: [name of principal investigator]
  - l. Save invoice and send to Sponsor through QuickBooks. Then save the invoice as PDF to appropriate customer/job folder

5. Reopen the invoice in QuickBooks & add the following line items:
  - ii. Select Admin Expense Assess item ID and Grant – Federal or Grant – Non-Federal class
  - jj. Enter amount as a negative at the same amount as the IDC
  - kk. Select Admin Income Assess item ID and Grant – Federal or Grant – Non-Federal class
  - ll. Enter amount as positive at the same amount as the IDC
  
6. Select List, Memorized Transaction List & select Admin Federal IDC Invoice JE or Admin Non-Federal IDC Invoice JE
  - a. Enter the date of the invoice
  - b. Enter the invoice # in the following format at Entry No. "INV1234"
  - c. Enter the amount of Federal or Non-Federal IDC assessment in the Debit column on Line 1, and in the credit column on Line 2
  - d. Enter the study customer/job name in the "Name" column on Line 1
  - e. Enter the invoice # in the Memo field & copy it down to all line items
  - f. Save & Close the journal entry

## **APPENDIX A**

### **NFFRE APPLICATION AND WOC APPROVAL PROCESS**

Applicant is first required to complete the WOC application process.

Applicant then completes the required NFFRE On-Boarding procedures under the instruction of the Program Specialist (PS) on ADP WorkForceNow. This includes being entered as an employee that is included in Time and Attendance and Payroll Summary, setting up direct deposit, eI9, and acknowledgment of Employee Handbook and company policies.

Before officially being hired as a NFFRE (WOC) employee, applicant must provide a copy of their WOC appointment and PIV exemption or PIV badge.

ED will provide Internal Controls training to employees within 90 days of hire. Once training is complete.

Please refer to the NFFRE Employee Handbook on ADP WorkForceNow.

## **APPENDIX B**

### **FUNDING PROCEDURES**

All mail is delivered directly to the NFFRE's administrative office by a postal employee each day. No other NFFRE staff member is allowed to open the mail. The Executive Director (ED) opens all mail and makes copies of any checks. Two copies are delivered with the check to the Program Specialist (PS) for preparation of the deposit.

ED confirms appropriateness of receipt relative to IRS, VA, and NFFRE regulations and guidelines. Immediately after receipt of original check, PS marks check "For Deposit Only" and prepares deposit slip and enters the check into the electronic accounting system. If there are any questions regarding type of revenue, account or class, item is coded "To Be Determined" and discussed with ED and/or accountant.

ED stores check(s) in safe or locked cabinet until deposit is to be prepared. Checks are to be deposited in a timely fashion, generally with 48 hours.

PS files original check transmittal document, if any, check stub and copy of check in corresponding project, vendor or other files as needed.

PS files a copy of each check and corresponding deposit summary as an attachment to the electronic deposit recorded in electronic accounting system.

All records are kept in locked files within an office that is locked when unattended.

PS deposits check remotely to the bank. ED verifies check deposits in the bank account and at Reconciliation. PS files the deposit slip electronically. ED will make deposits if PS is not available in order for checks to be deposited in a timely fashion.

Each investigator receives a quarterly P&L report for each of his/her projects detailing all deposits and/or expenses for each project or account.

## **APPENDIX C**

### **TRANSFER OF FUNDS**

While NFFRE receives funding from various sources for use for various purposes, funds are most commonly provided to NFFRE to support a particular research study to be conducted by a particular investigator. Funds for an active project are unrestricted to that project. (i.e., all expenditures must be in support of that particular project). The designation applies until that particular project is completed and all obligations to the sponsor (as mapped out in the CRADA drafted at inception of the project) have been met and the project is closed through the Institutional Review Board. At that point, if permitted by the sponsor, any residual funds transferred to the investigator's residual account become unrestricted board designated (i.e., no longer restricted to that particular project) and may be used for other purposes by that particular investigator. All expenditures, however, are still governed by NFFRE/VA and can only be used to benefit the VA. In some cases, however, the sponsor requires any residual funds to be returned to the sponsor.

Investigators who resign their NF/SG positions or who have a change in status that affects their WOC appointments will no longer meet the membership requirements outlined earlier. As a result, any fund balance and/or equipment inventory will be handled according to the appropriate policy. The transfer of funds policy stipulates that no funds will be transferred from NFFRE unless stipulated in a binding agreement. All other fund balances will remain NFFRE's for redistribution at the board's discretion and will be transferred to the unrestricted NFFRE Administration account. The policy also stipulates that no invoices for books, subscriptions, or dues will be paid within 90 days of a participant's anticipated resignation or non-qualifying change in status and that supply and equipment requests will not be processed within 30 days of resignation or non-qualifying change. Expenditures prior to resignation or change will only procure adequate material to cover anticipated needs prior to the researcher's departure. Stockpiling of supplies will not be permitted.

## **APPENDIX D**

### **PROCESSING BILLS, PURCHASE ORDERS AND PAYMENT REQUESTS**

All mail is delivered directly to the NFFRE administration offices by the VA Mail Service personnel. Executive Director (ED) opens mail distributes as appropriate.

ED briefly reviews bills (e.g., check for past due balances), and delivers to PS for processing,

If PS receives invoice indirectly through the investigator, he/she verifies investigator or designee authorization to pay and processes bill for payment.

All bills received either directly through the mail or indirectly through the investigator are approved for payment by the appropriate investigator or ED if for a NFFRE-administered project.

Bills for recurring or standard NFFRE administrative expenses (e.g., insurance, office supplies) are generally processed and then reviewed by ED when submitted for signature.

Refunds/overpayments are processed by ED reviewing supporting documentation as presented by PS. ED signs or co-signs checks the same as bills, PO, and requests for payment. Billing adjustments are made by PS with guidance and review by ED and external accountant.

ED confirms sufficient funds to cover each bill, codes the bill according to project, account and class. PS enters in electronic accounting system.

PS requests required number of blank checks from ED. ED retrieves checks from safe and confirms correct check number

PS prints checks, attaches supporting documentation, and passes to ED for review and signing of checks.

ED reviews supporting documentation for appropriateness of expenditure, accuracy of bills, timeliness of payment, absence of sales tax, etc.

ED signs checks or purchase orders. Checks or purchase orders over \$5,000 require a second signature from the secretary/treasurer of the NFFRE board of directors. Checks and documentation are returned to PS for copying and filing of copies and distribution. Checks are hand delivered, mailed or picked up by Clinical Research Coordinator if for research subject payments. Generally, all others are mailed to vendor.

Copies are filed in check run batches in chronological order in quarterly AP/Bank Deposit folders or, when appropriate, a copy of the check and backup documentation is filed in vendor or projects file.

All records are kept in locked files within an office that is locked when unattended.

All expenditures are reported to investigators on their monthly P&L reports.

Outstanding bills are reviewed monthly by PS and ED and PS follows up as necessary.

## **APPENDIX E**

### **PAYROLL PROCESSING**

The Program Specialist (PS) verifies the existence of sufficient leave accrual for any sick or vacation leave requested. Employees are able to request time off via ADP WorkForceNow, which keeps active record of time off balances.

A timecard must be entered on ADP WorkForceNow 12:00 p.m. on the Monday following the last day of the biweekly pay period.

The PS reviews all time entered on ADP WorkForceNow for accuracy and completeness. All new hires should enter their Direct Deposit information on ADP WorkForceNow within three (3) days of starting work with NFFRE. Timecards are reviewed Monday following the 12 p.m. deadline and payroll is processed through ADP WorkForceNow by 2 p.m. on Tuesday. The employee's net pay will be deposited into the employee's account Friday morning. If the PS is not available, ED processes as above.

ADP processes the payroll tax deductions per each payroll period. ADP is also responsible for processing individual deductions (e.g., 401K, healthcare, HSA contributions, etc.)

If PS is not available, ED processes as above.

Earned sick and annual leave records are available on ADP WorkForceNow under "Time Off – Time Off Balances".

All records are retained electronically through ADP WorkForceNow and are accessible by the employee at their convenience, including pay stubs, time off balances, and direct deposit information.

NOTE: VA may contract with University of Florida (UF) for employee services on NFFRE studies. In that case, UF employees continue to be paid in the usual fashion by UF and NFFRE reimburses UF.

**APPENDIX E****Monthly and Annual Review by Accountant**

The accountant will

review and reconcile the bank accounts monthly, or at least quarterly;

review financial statements (trial balance, balance sheet, profit & loss reports), correct any issues, and make journal entries as needed;

prepare the quarterly and annual payroll tax returns and schedule the ACH payment for any taxes due;

prepare 1099s and W-2s annually;

attend routine board meetings; assist with year-end closeout and production of final trial balance;

act as a liaison between NFFRE and audit firm;

and assist Executive Director and Program Specialist on an as needed basis

The Accountant will report any irregularities to the ED or the Secretary/Treasurer as appropriate.

## **APPENDIX G**

### **Month End Reports**

At the end of each month, the ED will prepare the monthly invoices to capture work performed (patient visits and research assistant time) and print out the monthly reports.

**Capturing Work Performed:** At the end of each month or quarter, the ED will confirm with the Clinical Research Coordinators that all patient visits for the ending month have been entered in the Patient Tracking Spreadsheet on the secured S/NFFRE/Regulatory drive or in the Clinical Trial Management System (CTMS), as applicable. See standard operating procedure for preparation of monthly invoices to capture work performed.

**Quarterly Reports:** Once the ED has completed the Monthly or quarterly Invoices to Capture Work Performed for the previous month, the month end or P&L reports should be sent by email to each active NFFRE investigator no less than each quarter.

ED will prepare and review statements, provide explanations if necessary, and present them at scheduled board meetings.

ED will prepare an overdrawn project account report before each quarterly meeting. ED will present and discuss any overdrawn project accounts with members.

ED will provide a narrative regarding the current financial position of the nonprofit at each scheduled board meeting.

**Under Memorized Reports:** Profit & Loss by Investigator – Process Group. Change all “To” dates to the last day of the previous month. Print.

Trial Balance, A/R Aging, Balance Sheet, Profit & Loss, and General Ledger are supplied to the ED and external auditors as requested.

After preparing month end reports, the ED will review outstanding invoices. Before contacting the sponsor, the ED will confirm with the Clinical Research Coordinator that there are no open queries or other items that may cause the sponsor to withhold payment.

The ED will contact the sponsor regarding any outstanding invoices to determine the reason for non-payment. The ED will address the non-payment issue immediately.

## **APPENDIX H**

### **RECONCILIATION OF BANK STATEMENTS**

Bank statements are promptly reviewed by ED for activity (e.g., verify that there has been no inappropriate debit activity) and authenticity of ED signature on checks when copy of check is provided.

Contract accountant posts all adjustments per bank statements and reconciles statements to corporate records.

ED confirms the reconciliation. ED will sign and date complete reconciliations.

PS files bank statements and corresponding reconciliation.

All records are kept in locked files within an office that is locked when unattended.

## **APPENDIX I**

### **TRAVEL PROCEDURES**

#### **Prior to Travel (approx. 3-6 weeks in advance, when possible):**

Fill out NFFRE Travel Request (Pre-Travel Authorization and Request for Reimbursement, when possible). All requests for travel must justify how the VA and its veteran patient population will benefit from the travel. Attach a copy of the program or conference announcement. Travelers making presentations must also provide a copy of their invitation or acceptance letter. This form should be signed by appropriate parties. Return fully executed form to NFFRE for approval and signature.

#### **Upon Completion of Travel:**

Complete the NFFRE Travel Request form (attached below) with actual expenses incurred, attach original receipts, and give to NFFRE office for review, approval, and reimbursement. Sign the form where indicated for post-travel. Submit to NFFRE.

Travel reimbursements made to the ED require board member approval and signature.

#### **VA Documentation:**

VA employees requesting NFFRE travel support must also provide an approved VA Form 0893 Advance Review of Offer to Donate Support for Official Travel as well as a memo from the Chief of Staff approving the travel. Both of these documents must be attached to the completed Travel Authorization Form for consideration of Foundation travel support.

## Travel Authorization

Travel Authorizations should be completed prior to making any travel arrangements. Agenda and/or meeting details must be attached.

Traveler Name

Phone

Address

Destination (City and State)

NFFRE Acct#

Name and Description of Meeting and Relevance to Research and/or Education

Proposed Departure Date

Proposed Return Date

Employment Status

☐ NFFRE

☐ VA

☐ University

Amounts Requested (Estimates Permitted)

Airfare

Lodging

Per Diem

Ground Transportation

Registration

Traveler's Signature

Date

PI Signature (if applicable)

Date

Executive Director Approval

Date