

EAST BAY INSTITUTE FOR  
RESEARCH & EDUCATION

non-profit affiliate of the VA Northern California Health Care System

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# Policies & Procedures

**This manual is under construction**

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## **I. Mission & Purpose of the Corporation**

The purpose of East Bay Institute for Research & Education (hereinafter referred to as “EBIRE”) is to facilitate and support non-merit research and educational activities at the Veterans Administration Northern California Healthcare System (VANCHCS). EBIRE is incorporated as a private, nonprofit corporation under the laws of the State of California and shall comply with all local, state and federal laws and with the common ethical principles of the U.S. Government and academic medicine.

NPCs exist to provide VA medical Centers with flexible funding mechanisms for the conduct of, and to facilitate functions related to the conduct of, VA approved research and education at one or more VA medical centers. The NPCs are not owned or controlled by the Federal government, nor are they an agency or instrumentality of the Federal government.

NPCs may facilitate the conduct of VA approved research. Each research project approved by the R&D Committee and each educational activity approved by the VA Education Committee is considered to be a VA research project or a VA educational activity regardless of the source of funding, the entity administering the funds, or the research or education site.

## **II. VA Oversight**

Although EBIRE is a private nonprofit corporation, it is a VA affiliated research and education corporation (VA NPC) that is subject to oversight by:

1. U.S. Department of Veterans Affairs (38 USC 7361 through 7366)
2. Public Law 111-163.

Oversight is primarily the responsibility of the Nonprofit Program Office (NPPO) which is part of Veteran Health Administration’s (VHA) Office of Research and Development. EBIRE is also subject to the scrutiny and review by the VA Office of the Inspector General (VA OIG).

## **III. Reporting to NPPO**

### **EBIRE Shall Report to the NPPO:**

1. EBIRE will promptly report the following to NPPO:
  - a. Change of physical address, email address, and phone numbers.
  - b. New Executive Director’s name and contact information.
  - c. New Board President or Chair name and contact information.
  - d. New principal accountant name and contact information.
  - e. Disputes with independent auditors other than over fees.

- f. All findings by any governmental auditors.
2. Significant adverse events such as:
- i. Major loss of property from fire, storm, or earthquake;
  - ii. All thefts and embezzlements regardless of amount;
  - iii. All threatened or actual litigation against EBIRE;
  - iv. Board votes for dissolution, merger, or significant transfer of assets;
  - v. Current or projected inability to meet financial obligations.
3. Additionally, by June 1 each year, EBIRE will submit an annual report to NPPO detailing the following:
- i. Major loss of property from fire, storm, or earthquake;
  - ii. All thefts and embezzlements regardless of amount;
  - iii. Outside independent auditors report and audited financial statements, if required by Handbook 1200.17;
  - iv. IRS Form 990 or 990 EZ Information Return;
    - Total revenue received
    - Amount received from governmental entities for research and the amount received from governmental entities for education
    - Amount received from all other sources for research and the amount received from all other sources for education
    - Detailed listing of amounts received from any source that exceeds \$25,000, as well as information that identifies the source
    - EBIRE expenses during the year including:
      - Salary expenses for researchers, education staff, and administrative personnel
      - Amounts of expenses incurred for direct support of research and for direct support of educational activities
      - A detailed listing identifying payees if the amount expended to the payee exceeded \$50,000
      - Amounts expended during the year for travel conducted in conjunction with research and the amount expended for travel in conjunction with educational activities.
  - v. Certifications signed by the Executive Director that each director, officer, and key employee has certified awareness of, and compliance with, the conflict of interest policy and that directors and key employees have all fulfilled the mandatory internal controls training requirement;
  - vi. EBIRE's physical address along with the name of the VA medical center(s) served by EBIRE.

#### **IV. Governance & Personnel**

## **Board of Directors**

In accordance with EBIRE's by-laws, a Board of Directors is established. The Board shall consist of at least six statutory members.

1. Federal Statutory Members, consisting of the following VA employees holding specific medical center positions include:
  - a. Medical Center Director
  - b. Chief of Staff
  - c. Associate Chief of Staff for Research (or equivalent)
  - d. Associate Chief of Staff for Education (or equivalent)
  
2. Non-Federal Statutory Members must be neither officers nor employees of the Federal government, and who have backgrounds in business, legal, financial, medical, or scientific expertise of benefit to NPC operations. Non-Federal Statutory Members shall include:
  - a. President/Executive Director
  - b. Community Member with Appropriate Background

## **Board Meetings**

The EBIRE Board will complete the following fiduciary requirements:

1. Meet at least quarterly. The agenda and the supporting documentation for the meetings will be distributed in advance in order to allow members ample time to prepare for the meeting.
2. Review the by-laws every three to five years and update them as required.
3. Review EBIRE's Policies & Procedures periodically.
4. Review the mission statement at least every three years and update as needed.
5. Establish short and long term goals for EBIRE.
6. Approve an administrative operating budget for EBIRE annually.
7. Review and approve EBIRE's financial policies.
8. Provide financial oversight including:
  - i. Approving the selection of an independent outside auditing firm.
  - ii. Meeting with the auditor independently from staff.
  - iii. Reviewing and monitoring:

1. Audit and auditors' management letters
  2. IRS Form 990 Information Return and related schedules
  3. Internal financial statements
  4. Internal controls
9. Supervise the President/Executive Director including:
- i. Establishing and maintaining a position description.
  - ii. Approving the annual performance evaluation review.
10. Undergo regular Governance Training. Board members will annually review and sign the conflict of interest statement as described in VHA Handbook 1200.17 and serves as a portion of the required Conflict of Interest training.

Written expectations will be provided for board members. An orientation process will be established for new board members. The Board will conduct an annual evaluation of its own performance.

No compensation will be paid to EBIRE's board members.

### **Board Meeting Minutes**

Minutes of all Board of Directors meetings will be maintained by EBIRE's Executive Director. The minutes will include the following:

1. Date and time meeting begins and ends
2. Members present
3. Agenda items
4. Detailed discussion and deliberation
5. Board decisions and any follow-up actions required

The minutes will be approved by the Board and signed by the Board Secretary and Executive Director. The minutes will be maintained according to the by-laws, state and Federal law.

### **New Board Member Orientation**

Board orientation is the process of educating board members about their roles, responsibilities, EBIRE, and Board management.

The orientation process will include and take place within 30 days of appointment:

1. Welcome letter and appointment/term.
2. Board of Director's Information:
  - a. Logistical details of the next board meeting
  - b. Schedule of board meetings
  - c. Board of directors roster
  - d. Board of directors expectations and meeting practices
  - e. Conflict of Interest Policy Training and disclosure form
  - f. Internal Controls Training
  - g. Background regarding current issues before the Board
  - h. Minutes for the last four board meetings
  - i. Agendas for the previous two board meetings
3. General information about EBIRE:
  - a. Statutory authority
  - b. VHA Handbook 1200.17
  - c. Bylaws
  - d. The EBIRE Policy and Procedure Manual including the Mission Statement
  - e. Most recent annual report
  - f. Summary of insurance coverage
  - g. Last completed audit and IRS Form 990
  - h. Approved operating budget for the current year

#### **EBIRE Code of Ethics**

Each person associated with EBIRE must conform to the highest generally-accepted ethical standards, which should extend beyond compliance with applicable laws and regulations in business situations and to govern behavior where no existing regulations provide guidelines. Every board member and employee must exhibit honesty, integrity, loyalty, responsibility, fairness, and citizenship in all



instances. It is each person's responsibility to apply these ethical standards in business decisions where specific rules do not provide all the answers.

In determining compliance with this standard in specific situations, each person should consider the following:

- Is my action legal?
- Is my action ethical?
- Does my action comply with the policies of the EBIRE?
- Am I sure my action does not appear inappropriate?
- Am I sure that I would not be compromised if my action became known with the publicly?
- Am I sure my action meets the generally-accepted standards of ethics and ethical behavior?

Each person should be able to answer "yes" to all of these questions before taking any action.

This Code of Ethics will be posted visibly at all EBIRE locations and all employees will receive periodic reminders of its importance to EBIRE.

### **Conflicts of Interest**

A conflict of interest, a.k.a. "self-dealing transaction," may exist when the interests or concerns of a board member the executive director could be seen as competing with the interests or concerns of EBIRE. There are a variety of situations that raise conflict of interest concerns, including but not limited to the following:

1. Financial Interests: A conflict may exist where an interested party directly or indirectly benefits or profits as a result of a decision, policy or transaction made by EBIRE. Examples include situations where:
  - i. EBIRE contracts to purchase or lease goods, services or properties from an interested party.
  - ii. EBIRE offers employment to an interested party, other than a person who is already employed by EBIRE.
  - iii. An interested party is provided with a gift, gratuity or favor of a substantial nature from a person or entity that does business or seeks to do business with EBIRE.
  - iv. An interested party is gratuitously provided use of EBIRE's facilities, property or services.
  - v. EBIRE adopts a policy that financially benefits an interested party.

Note that a financial interest is not necessarily a conflict of interest. A financial conflict of interest exists only when the board decides a person with a financial interest has a conflict of interest.

2. Other Interests: A conflict may exist where an interested party obtains a non-financial benefit or advantage that he/she would not have obtained absent his/her relationship with EBIRE.

Examples include:

- i. An interested party seeks to obtain preferential treatment by EBIRE or recognition for himself/herself or another interested party.
- ii. An interested party seeks to make use of confidential information obtained from EBIRE for his/her own benefit (not necessarily financial) or for the benefit of another interested party.
- iii. An interested party seeks to take advantage of an opportunity or enables another interested person or other organization to take advantage of an opportunity that he/she has reason to believe would be of interest to EBIRE.
- iv. EBIRE adopts a policy that provides a significant non-financial benefit to an interested party.

### **Disclosure of Potential Conflicts of Interest**

An interested party is under a continuing obligation to disclose any potential conflict of interest as soon as it is known or reasonably should be known.

An interested party shall complete the Conflict of Interest form to fully and completely disclose the material facts about any potential conflicts of interest. The disclosure statement and Affirmation of Compliance shall be submitted upon his/her association with EBIRE, and shall be reviewed annually thereafter. An additional disclosure statement shall be filed whenever a potential conflict of interest arises.

Disclosure statements will be submitted as follows: For board members, the disclosure statements shall be provided to the EBIRE Executive Director. Copies shall be available for review to the Secretary/Treasurer of the Board.

In the case of staff with significant decision-making authority, the disclosure statements shall be provided to the Executive Director. In the case of the Executive Director, the disclosure statement shall be provided to the Secretary/Treasurer of the Board.

In all cases, the recipient is the designated reviewing official responsible for bringing potential conflicts to the Board's attention. The Executive Director shall file copies of all disclosure statements with EBIRE's official corporate records.

### **Procedures for Review of Potential Conflicts**

Whenever there is a reason to believe that a potential conflict of interest exists between EBIRE and a Board member or the Executive Director, the Board of Directors shall determine the appropriate response. This shall include, but not necessarily be limited to, invoking the procedures described below with respect to a specific proposed action, policy or transaction. The designated reviewing official has a responsibility to bring a potential conflict of interest to the attention of the Board

promptly for action at the next regular board meeting or during a special meeting called specifically to review the potential conflict of interest.

### **Procedures for Addressing Conflicts of Interest**

Where a potential conflict exists between EBIRE's interests and an interested party the Board of Directors shall consider the matter during a meeting of the Board. The following procedures shall apply:

1. An interested party who has a potential conflict of interest with respect to a proposed action, policy or transaction shall not participate in any way in, or be present during, the deliberations and decision-making vote of the Board with respect to such action, policy or transaction. However, the interested party shall have an opportunity to provide factual information about the proposed conflict of interest and/or action, policy or transaction. Also the Board may request that the interested party be available to answer questions.
2. The other members of the Board may approve the proposed action, policy or transaction upon finding that it is in EBIRE's best interests. The Board shall consider whether the terms of the proposed action, transaction or policy are fair and reasonable to EBIRE and whether it would be possible, with reasonable effort, to find a more advantageous arrangement with a party or entity that is not an interested party.
3. Approval by the other members of the Board shall be by vote of a majority of Directors in attendance at a meeting at which a quorum is present. An interested party shall not be counted for purposes of determining whether a quorum is present, or for purposes of determining what constitutes a majority vote of Directors in attendance.
4. The minutes of the meeting shall reflect that the conflict disclosure was made to the Board, the vote taken, and, where applicable, the abstention from voting and participation by the interested party. Whenever possible, the minutes should frame the decision of the Board in such a way that it provides guidance for consideration of future conflict of interest situations.

It is EBIRE's policy to refrain from hiring subordinates with a financial, social, familial or romantic relationship with any employee or board member.

### **Violations of Conflict of Interest Policy**

If the Board of Directors has reason to believe that an interested party has failed to disclose a potential conflict of interest, it shall inform the person of the basis for such belief and allow the person an opportunity to explain the alleged failure to disclose. If the Board decides that the interested party has in fact failed to disclose a possible conflict of interest, the Board shall take such disciplinary and corrective action as the Board shall determine.

EBIRE and the Board of Directors follow policies and procedures of this manual that are consistent with VHA Handbook 1200.17. All directors and employees will read the Handbook within 30 days of their appointments.

1. The Board of Directors reviews the mission statement of the Institute at least every three years. Documentation of this will be maintained in the meeting minutes.
2. The Board of Directors establishes/reviews short and long term goals for EBIRE.
3. EBIRE will conduct an assessment of its programs by periodically surveying its Principal Investigators and assessing feedback from stakeholders.
4. EBIRE will obtain and maintain a Federal Wide Assurance (FWA).

### **President/Executive Director**

The EBIRE President/Executive Director (ED) is appointed to the position following approval by the Board of Directors and via an appointment letter endorsed by the VANCHCS Medical Center Director. The ED shall be appointed via a contracted employment relationship, whereas EBIRE staff shall be hired through traditional employee/employer processes. The ED's hiring contract shall accompany the appointment letter, with approval by the VANCHCS's assigned General Counsel STAR attorney.

EBIRE's ED is responsible for overseeing day-to-day operations. Such duties may include, but are not limited to:

1. For outside, non-statutory directors, approving appointments to the Board of Directors.
2. Reviewing contracts, agreements or collaborations between EBIRE and other entities for compliance with federal, VA and nonprofit guidelines.
3. Establishing, with appropriate professional assistance, necessary and appropriate internal accounting and management control systems.
4. Maintaining appropriate fiscal and management records of all research activities and submit regular reports to the Board of Directors for their review.
5. Providing an annual administrative budget to the Board of Directors for review.
6. Preparing and/or reviewing all appropriate reports and annual filings made to State, Federal and VA authorities (annual filings with the Secretary of State, Annual Report to VA/NPPO, IRS Form 990 Information Return, Research & Development Information Systems Annual Report, and reports to VA Regional Counsel).
7. Annually certifying that signed conflicts of interest disclosure forms are on file for each board member.
8. Certification of compliance with Internal Controls Training and Conflict of Interest Training.

Administrative and/or accounting staff may be employed by the ED as required to effectively carry out EBIRE's operations. Such staff will be managed by the ED. Accounting staff will handle EBIRE's

day-to-day financial operations, including, but not limited to, depositing of funds, maintenance of all necessary EBIRE accounts, processing accounts receivable and payable, purchase of all equipment and supplies, writing appropriate checks for signature by the ED and/or other designated official, and monthly reconciliation of accounts. Administrative staff will handle EBIRE's day-to-day administrative operations, including, but not limited to, reviewing and revising contracts as necessary, maintenance of administrative and Board documents, scheduling Board meetings and transcribing minutes.

### **Employee Handbook**

The Employee Handbook (current revision) is the official document approved by the EBIRE Board of Directors, and is intended to provide detailed personnel practices for all paid staff of EBIRE.

NOTE: EBIRE is an equal opportunity employer and makes employment decisions on the basis of merit. EBIRE is committed to compliance with all applicable laws providing equal employment opportunities. This commitment applies to all personas involved in the operations of the organization and prohibits unlawful discrimination by any employee of EBIRE, including supervisors and coworkers. EBIRE policy prohibits unlawful discrimination based on race, color, creed, gender, religion, marital status, age, national origin or ancestry, physical or mental disability, medical condition including genetic characteristics, sexual orientation, or any other consideration made unlawful by federal, state, or local laws. It also includes a perception that anyone has any of those characteristics, or is associated with a person who has or is perceived as having any of those characteristics. All such discrimination is unlawful.

### **Control Environment**

EBIRE's board members, executive director and employees will maintain effective internal controls in the organization. Duties will be sufficiently segregated so that those initiating transactions are not also approving them and recording them. Where this is not possible due to lack of administrative personnel, then board members will undertake the responsibilities to approve and/or review transactions and documents, e.g. the Secretary/Treasurer may receive, open, review, and approve the monthly bank statements before forwarding them to the President/Executive Director for preparation of the monthly bank reconciliations. Similarly, after the bank reconciliations are prepared, the Secretary/Treasurer may review and approve them.

Board members and the executive director will strive to maintain the right "tone at the top," which means exhibiting the highest ethical behavior and thereby setting the proper example for all people in and around EBIRE. Under no circumstances will the Code of Ethics and the highest standard of ethical behavior be waived or overridden. Similarly, no one will waive or override any of EBIRE's established internal controls.

Periodically, the ED will remind everyone in the organization that EBIRE truly values the highest ethical behavior and having effective internal controls. These reminders will be done by email or other messaging. As part of these periodic reminders, the ED will solicit suggestions for improvements.

Self-assessment is particularly important any time there are major changes occurring in EBIRE, such as rapid growth or management changes. Records of any remedial actions taken will be kept.

## V. Operations: Research

### Research Activities

1. **Project Approval:** All research projects must receive a formal approval by the VA Research & Development Committee (R&DC) and other appropriate committees and subcommittees. Such committees and subcommittees may include: R&DC, Education Committee, Institutional Review Board (IRB), Subcommittee on Research Safety, and Subcommittee on Animal Studies.

Expenditures for these studies should be in compliance with VHA Handbook 1200.17.

2. **Principal Investigators:** The Principal Investigator (PI) for each project must hold a VA appointment. The PI for each project is responsible for providing candidates and supervising personnel for their research activity. EBIRE will pay research personnel from the appropriate research accounts funds only upon request and approval from the appropriate Principal Investigator and EBIRE President/Executive Director.
3. **Research Personnel:** The PI for each research project or activity is responsible for managing personnel involved in research. EBIRE will pay said personnel on request from the PI from the study's designated funds.
4. **Equipment:** All equipment purchased with EBIRE funds belongs to EBIRE alone. An inventory of capitalized business property will be maintained by EBIRE.

Once research funds and research equipment are transferred to a VA affiliated nonprofit such as EBIRE those resources (with the exception of EBIRE overhead deductions) are VA research property. These resources do not belong to an investigator.

5. **Research Personnel, Contracts, & Consultants:** Any VA employee, including EBIRE board members, may not work for pay from EBIRE on government time. Any salary earned as EBIRE employees must be for hours worked outside their VA tour of duty and must be for performing duties other than their usual and customary VA work. A VA employee may not receive pay from a non-governmental source at the direction of the employee's Federal supervisor for services performed off-duty that is part of his official duties. For each employee, a time card showing both VA and non-VA hours worked must be submitted to EBIRE for each pay period.

A consultant is an individual that has been contracted to complete a particular aspect necessary to an authorized project. Payment for services will be made upon completion of the contract as a whole or as sections of the contract come due. The consultant must invoice the PI as well as submit a progress report or summary, which the PI attaches to a "Payment for Contractual Services" form that will be submitted to and approved by the Executive Director.

## **6. Objectivity in Research – Investigator Disclosure of Financial Conflict of Interest:**

It is the policy of EBIRE that objectivity in the conduct of research must be maintained and that there are procedures to identify potential financial conflicts of interest. If such are identified, there will be procedures for managing, mitigating or eliminating them.

- a. When a project is initiated using the EBIRE resources there is a specific investigator certification requirement regarding financial conflict of interest.
- b. If potential financial conflict of interest is identified for any EBIRE administered project, the procedures defined in VANCHCS Memorandum \_\_\_-\_\_\_-\_\_\_ - Conflict of Interest in the Conduct of Research, will be effected.

## **7. Promoting Objectivity in Research – Additional Requirements for PHS Awards:**

The purpose of the COI Regulations is to promote objectivity in research by establishing standards that provide a reasonable expectation that the design, conduct, and reporting of research funded by the PHS under grants, cooperative agreements or contracts will be free from bias resulting from the financial conflicts of interest of an Investigator. The NIH Office of Extramural Research Conflict of Interest website contains helpful information and resources about the COI Regulations. See [http://grants.nih.gov/grants/policy/coi/coi\\_faqs.htm](http://grants.nih.gov/grants/policy/coi/coi_faqs.htm).

The Department of Veterans Affairs (VA) is responsible for developing agency specific guidance regarding the management of financial conflict of interest in research. Because all research managed by EBIRE is VA research and because employees engaged in such research hold VA paid or VA Without Compensation (WOC) appointments the VANCHCS policy on Conflict of Interest in the Conduct of Research is applicable to EBIRE activities. In addition dually appointed faculty members are subject to the requirements of University Affiliate Institutions regarding the management of financial conflict of interest. Any project that involves human subjects research is subject to both VA and those University Affiliates (if applicable) policy and requirements regarding financial conflict of interest in the conduct of human research.

PHS agencies including the NIH require that each investigator disclose to a designated representative of the institution (EBIRE) all significant financial interests of the investigator that would reasonably appear to be related to the investigator's institutional responsibilities. Processes for disclosing and for managing any significant financial conflict of interest are described in this policy.

## **8. Definitions**

1. Disclosure of significant financial interests (SFI) means an Investigator's disclosure of significant financial interests to an institution, i.e., EBIRE.
2. Financial conflict of interest (FCOI) means a significant financial interest that could directly and significantly affect the design, conduct, or reporting of PHS-funded research.

3. Institution for purposes of this policy means EBIRE. However, by virtue of their appointments with VANCHCS and/or University Affiliates could include those two institutions.
4. Institutional Responsibility means an Investigator's professional responsibilities on behalf of the Institution (but also to include VA and University Affiliates if relevant to a EBIRE-administered award); these may include research, teaching/education, clinical activities, committee memberships or other administrative responsibilities.
5. Investigator means the Project Director or PI and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded by the PHS, or proposed for such funding.
6. Significant Financial Interest (SFI) means: A financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse/domestic partner and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities or that could impact the conduct of an award:
  - i. With regard to Publicly Traded Entities: remuneration or value exceeding \$5,000 when aggregated for an Investigator and the Investigator's spouse/domestic partner and dependent children from a single entity, including salary, consultant payments, honoraria, paid authorship, equity interest (stock, stock option or other ownership interest) during the prior 12 months.
  - ii. With regard to Privately Held Entities: payments or value exceeding \$5,000 when aggregated for an Investigator and the Investigator's spouse/domestic partner and dependent children from a single entity during the prior 12 months or when the Investigator and the Investigator's spouse/domestic partner and dependent children hold any equity interest (stock, stock option, or other ownership interest).
  - iii. With regard to Intellectual Property: intellectual property rights and interests (patents, copyrights) upon receipt of income related to such rights and interests if paid by an entity other than VA or University Affiliate.
  - iv. With regard to Travel: any reimbursed or sponsored travel related to the Investigator's Institutional Responsibilities during the prior 12 months, with the exception of travel that is reimbursed or sponsored by a Federal, state, or local government agency; an institution of higher education; an academic teaching hospital; a medical center; or a research institute that is affiliated with an institution of higher education. Travel reimbursed by EBIRE is not subject to reporting requirements.



- v. Significant Financial Interest does not include:
  - a. Salary, royalties, or other remuneration paid by the VA, University Affiliate or EBIRE to the Investigator if the Investigator is currently employed or otherwise appointed, including intellectual property rights assigned to the VA and/or University Affiliate and agreements to share royalties related to such rights;
  - b. Income from investment vehicles, such as mutual funds and retirement accounts;
  - c. Income from seminars, lectures, or teaching engagements sponsored by a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education;
  - d. Income from service on advisory committees or review panels for a Federal, state, or local government agency, an institution of higher education, an academic teaching hospital, a medical center, or a research institute affiliated with an institution of higher education.
  
- vi. For consideration when completing disclosure forms, Personal Financial Interest with an entity that is considered reasonably related to an Investigator's research study would be a case in which:
  - a. Entity sponsors research in which the investigator is directly involved;
  - b. Entity has financial interests that could reasonably be considered to have a potential influence on the design, conduct or reporting of investigator's research/scholarship;
  - c. Entity has a reasonable possibility of being financially affected by investigator's research/scholarship;
  - d. Entity makes gifts to VA, University Affiliate or EBIRE that benefit investigator's research/scholarship (including equipment gifts or loans);
  - e. Entity makes a product that is under study in research in which investigator is involved;
  - f. Entity licenses VA or University Affiliate intellectual property in which investigator has a financial interest;

- g. Entity has a Materials Transfer Agreement or Human Tissue Agreement (MTA/HTA) to provide materials used in investigator's research or for materials provided by investigator to the company/organization;
- h. Entity sponsors or makes a product that is under study in human subjects in which investigator is directly or indirectly involved.

## 9. Disclosure and Review Processes

Initial Proposal and Annual Report Related Submissions and Review: The PI must complete the Disclosure of Financial Interests form at initial PHS-funded proposal submission for new award applications and annually in conjunction with submission of PHS-funded non-competing continuation awards. At that time s/he will determine whether any other person, regardless of title or position, responsible for the design, conduct, or reporting of research has a significant financial conflict of interest that could affect the conduct of the award. If such is a possibility then the PI will identify those parties for appropriate follow-up by EBIRE Administration.

If a Significant Financial Interest that reasonably appears to be related to an Investigator's Institutional Responsibilities is disclosed that information along with supporting documentation shall be forwarded to EBIRE's President/Executive Director. In coordination with VA and University Affiliates (for dually appointed faculty) COI Managers and relevant policies or procedures, a determination as to whether any of the disclosed Significant Financial Interests of the Investigator are related to the project and whether the financial interest could directly and significantly affect the design, conduct, or reporting of the project (a FCOI) will be made. If there is an FCOI it will be either eliminated, reduced or managed depending on the specific case. If managed, a management plan will be developed in conjunction with VA and/or University Affiliates and appropriate notifications will be reported to PHS.

Notice of Change in Investigator's Significant Financial Interests OR Addition of Investigator with Significant Financial Interest Submissions and Review: If at any point there is the addition of an Investigator new to the project who might have a Significant Financial Interest or a change in an existing Investigator's financial situation that meets the threshold for SFI disclosure and review of significant financial interest the Principal Investigator must disclose that change within 30 days of addition of the new Investigator or of discovering or acquiring a new SFI. That is accomplished through the use of the Disclosure of Financial Interests form for review and processing as described above. If the Investigator is dually appointed Stanford will be informed of such disclosures.

## 10. Management of Financial Conflicts of Interest

Examples of conditions or restrictions that might be imposed to manage, reduce or eliminate conflicts of interest include but are not limited to:

- Public disclosure of significant financial interests;
- Monitoring of research by independent reviewers;
- Modification of the research plan;

- Disqualification from participation in the portion of the NIH funded research that would be affected by significant financial interests;
- Divestiture of significant financial interests;
- Severance of relationships that create conflicts.

Enforcement mechanisms and sanctions will be managed in coordination with applicable EBIRE, VA and University Affiliate policies.

#### **11. Agency Notifications (PHS ONLY)**

Upon receipt of an award from the Public Health Service and prior to the expenditure of any funds, as well as within 60 days for any new interest that EBIRE identifies as conflicting subsequent to the Institution's initial report under the award, EBIRE is obligated to notify the sponsoring institute or agency of any FCOI associated with that award. In addition EBIRE will provide annual updates on any previously-identified FCOI for the duration of the research project. If an FCOI is identified at the time a proposal is submitted, and that proposal is subsequently awarded, or if an FCOI is identified subsequent to the award of the project, EBIRE must prepare a notification to the eRA Commons FCOI Module. That notification is to consist of the following:

- grant number;
- PI or contact PI designee;
- name of Investigator with the FCOI;
- name of the entity with which the Investigator has an FCOI;
- nature of FCOI, e.g. equity, consulting fees, travel reimbursement, honoraria;
- value of the financial interest (in pre-specified dollar ranges) or a statement that a value cannot be readily determined;
- a description of how the financial interest relates to NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research;
- key elements of the Institution's management plan including:
  - role and principal duties of the conflicted Investigator in the research project;
  - conditions of the management plan;
  - how the management plan is designed to safeguard objectivity in the research project;
  - confirmation of the Investigator's agreement to the management plan;
  - how the management plan will be monitored to ensure Investigator compliance;
  - other information as needed.

A copy of the notification must be kept with the project records. (Note that this notification requirement currently applies only to the Public Health Service, including the National Institutes of Health (NIH).)

#### **Other Requirements:**

**Public Accessibility:** Prior to the expenditure of funds, EBIRE will make certain that information concerning FCOIs held by senior/key personnel is publicly accessible by a written response to any requestor within five business days of a request.

## 12. Sub-Awards

If EBIRE carries out PHS-funded research through subawardees, contractors, or collaborators, EBIRE must take reasonable steps to ensure that the entity has its own policies in place that meet the requirements of the PHS policy or that investigators working for such entities follow EBIRE policies.

## 13. CRADAs

- i. **Confidentiality Negotiation (CDA/NDA)**
- ii. **Pre-Qualification**
- iii. **CRADA Negotiation**
- iv. **CRADA eRegistry**
  1. The CRADA eRegistry is a webpage designed for the entry, tracking, and verification of CRADAs within the VA. EBIRE shall enter all contracts into the eRegistry within 30 business days of contract execution.
  2. To access the eRegistry:
    - a. Follow this link:  
<http://vaww.pubtracker.research.cfdi.webdev.va.gov/crada/logout.cfm>
      - Log in using the username “EBIRE” and password “crada 30”
      - Click on the tab “Enter a New CRADA” at the top left of the screen
    - b. When entering a CRADA into the eRegistry, several pieces of information are needed. Note that all information required by the eRegistry can be found within either the CRADA or study protocol, such as:
      - Study Title
      - Project Identifier (if one exists)
      - Common name of study ( if one exists)
      - Names of project collaborators
      - Names of CROs, SROs, or SMOs (if applicable)
      - Study category and phase
      - Station number of the appropriate VA medical center
      - NPC name (generally EBIRE)
      - Name of VA attorney, location, and regional counsel office
      - Name of the study PI
      - CRADA negotiation start and execution dates
    - c. Populate the form according to the instructions next to each text field. Upload a PDF copy of the CRADA using the file upload tool at the bottom of the page.
    - d. When done, prepare a one-page document (either computer-generated or my hand) that includes the following information, then file on the top of the CRADA in the project binder
      - Date

- Name of person who entered
- Initial & file

#### **14. Eligibility for Use of EBIRE as Administering Organization**

It is the policy of EBIRE to administer funds provided to support VA research or education activities within the guidelines approved by the Board of Directors and in accordance with applicable regulatory requirements.

#### **15. Principal Investigator Status**

- i. VANCHCS Memorandum No. \_\_\_-\_\_-\_\_ (*under revision*) sets forth the requirements for establishing PI eligibility status for research activities. EBIRE will administer funds only for those investigators who meet these requirements and have been approved as Principal Investigators.
- ii. From time to time there may be instances wherein an investigator wishes to submit a funding application but has not yet obtained PI eligibility approval as required by policy. In such cases, and assuming all other requirements are met, the President/Executive Director may approve the application for submission to the funding agency with the clear understanding that, should PI eligibility not be approved, EBIRE will request withdrawal of the application from the funding entity.
- iii. PI status will terminate when the PI resigns, transfers or retires from VAPAHCS or requests termination of such status. Guidelines for distribution of remaining funds, both from active awards and residual/donation accounts, and related equipment are described below:
  1. Transfer of Donated and/or Residual Funds - If the PI is transferring to another VA and will continue an ongoing research or education activity, residual/donation funds may, at the discretion of the Board of Directors, be transferred to a VA-affiliated NPC. Further, equipment that was acquired primarily for use by the departing investigator may be considered for transfer. In reviewing such requests the Board will consider donor-imposed restrictions on residual funds, whether the transfer will support VA research, and EBIRE/VANCHCS needs.
  2. In these cases the PI should submit a memorandum to the Board of Directors, through the President/Executive Director, delineating what is requested for transfer.
  3. No residual funds will be transferred other than to a VA-affiliated NPC. Because EBIRE exists to facilitate VA research and because the funds administered by EBIRE become EBIRE funds, residual funds must be used in support of VA research and education. Therefore, transfer to other than a VA or VA-affiliated NPC would not be in furtherance of VA research or education. The ability of the PI to

exercise control over residual funds is solely at the discretion of the Board of Directors.

4. Cessation of Research Activities, Retirement or Death – When a PI ceases engaging in research, retires or dies, residual funds and equipment will revert to EBIRE administration for redistribution.
  5. Transfer to a For-Profit Entity – No funds or equipment will be transferred to such an entity.
  6. Under VA Handbook 1200.17 any funds remaining after the completion of a research project must be used for the general support of VA research.
  7. These residual funds are the property of EBIRE and are subject to policies and procedures established by the Board of Directors. Such policies and procedures are consistent with applicable federal and state statutes and regulations. When legally allowable, exceptions to standard policies and procedures will be granted only after review and approval of the Board, and will be granted only in extraordinary circumstances. Nonetheless, it is incumbent on the EBIRE Board of Directors to consider the interests of the Corporation in deliberating such matters. Decisions of the Board are final, and after each request has been considered, a formal response will be sent to the principal investigator by the Board.
- i. The Executive Director will determine whether all outstanding financial obligations related to the project have been fully met. The Corporation may hold back as much as 20% of the remaining project funds for up to 90 days to cover any costs that may become apparent after the transfer has been executed. Since restricted funds are bound by contractual obligations outlined in clinical trial agreements with the Sponsor, the principal investigator must obtain from the project Sponsor written permission to transfer the project to another 501 (c) (3) non-profit organization, or to a state or federal entity. The Corporation also must receive a letter from the recipient organization accepting responsibility for the research project and the related funds and/or equipment, along with appropriate documentation certifying its non-profit status.
  - ii. To ensure the smooth, orderly transfer of a research or education project, the non-profit organization from which the principal investigator is transferring must be informed of such move at least three (3) months in advance of the transfer date. The Board of Directors has sole authority to approve such a transfer. Following approval by the Board, the principal investigator is responsible for the cost and risk of shipping equipment to the new location.

Option 2 (Internal Transfer): The project Sponsor must be notified of any substantial changes in the status of the designated principal investigator on an active research or education project. Such changes cannot be made without prior written approval of the project Sponsor together with the completion of an amendment changing the principal investigator name. If the designated principal investigator of an active research project is terminated from the study, or in the event of death, a written request to assign a replacement investigator must be submitted by the Executive Director to the project Sponsor. The Board of Directors must certify that the new principal investigator has the expertise, knowledge and technical support to perform the study consistent with the terms of the study protocol and the clinical trial agreement. The transfer of responsibilities to the new investigator must be approved by the medical center's R & D Committee.

- i. Corporation funds associated with the active research project and/or Corporation-owned equipment necessary for the conduct of the project will be transferred to the replacement principal investigator upon written approval from the project Sponsor.

#### A. Residual Funds

Funds donated to EBIRE for the general support of an investigator's research or education activity and funds remaining from completed projects are generally referred to as "residual funds." Use of such funds for general research and education purposes is predicated first on fulfilling all requirements specified by the Sponsor, or any other donor at the time funds are initially received by the Corporation. Residual funds may be used only for scientific and professional expenditures and must further the conduct of VA-approved research projects or educational activities.

#### B. Transfer of Residual Funds

Transfer Option 1: In the event an investigator terminates his or her employment at the VANCHCS, the disposition of residual funds remaining in the investigator's general residual account will be subject to the discretion of the Board. A request for transfer of residual funds must be submitted to the EBIRE Board of Directors at least three months prior to the anticipated date of termination.

Transfer Option 2: In the event an Investigator should die or terminate his or her employment at the VA medical facility, or with the Corporation itself, all residual funds remaining in the investigator's general residual account will be transferred to the Corporation's administrative account and used at the discretion of the Board of Directors. Because the donor acknowledgement letter reflects the Board's view that all funds donated to

the Corporation are intended to support VA projects and research and/or educational activities at the VANCHCS, the Corporation does not allow transfer of residual funds or Corporation-owned equipment.

Transfer Option 3: In the event an investigator terminates his or her employment at the VANCHCS, the disposition of residual funds remaining in the investigator's general residual account will be subject to the discretion of the Board. Generally, if the investigator is transferring to another VA facility with an affiliated non-profit Corporation, the Board will determine the maximum allowable balance of funds to be transferred from the investigator's account. The remaining balance, if any, will be transferred to the Corporations' administrative account and will be used at the discretion of the Board of Directors. Because the donor acknowledgement letter reflects the Board's view that all funds donated to the Corporation are intended to support VA projects and research and/or educational activities at the VANCHCS, the Corporation does not allow transfer of residual funds or Corporation-owned equipment.

### C. Death or Disability of an Investigator

In the event an investigator should die or become unable to conduct research, the Executive Director will immediately inform the Sponsor of each of the investigator's ongoing projects. With the Sponsor's permission, a project may be transferred to another investigator affiliated with the medical center. If no other investigator is able to assume responsibility for a project, reports completed to date will be sent to the Sponsor and any funds remaining, after all outstanding obligations have been paid, will be returned to the Sponsor. All residual funds remaining in the investigator's general residual account will be transferred to the Corporation's administrative account and will be used at the discretion of the Board of Directors.

## **16. Responsibilities of Investigators for the Administration of Awards**

EBIRE's policies and procedures concerning the negotiation, acceptance, management and administration of projects and grants are contained in the section of this Manual labeled, "Acceptance and Deposit of Funds." Those portions applicable to Principal Investigators/Project Directors are summarized below for guidance and compliance:

- a. PIs are obligated to observe established terms and conditions.
- b. Such obligations include, but are not limited to: (a) expenditures which are not clearly permitted by the terms of a contract or grant shall not be authorized by a PI or Project Director without consultation with cognizant fiscal and administrative officials and clearance with the funding agency if doubt still exists, (b) the filing of reports by the dates agreed upon, (c) observance of requirements to protect patent rights, and (d) the allowance of adequate lead time on applications for project renewal or extension.



- c. Once a contract, grant agreement, or sub-contract have been executed, the subsequent actions incident to performance of the agreements are ordinarily carried out by the Principal Investigator, interacting with the R&D Office and with the other party to the project agreement.
- d. Proper termination of a contract is, of course, of great importance. The President/Executive Director or designee should be assured that the property aspects of the transaction are clear, and there should be clear assurance from the Principal Investigator that EBIRE has satisfied its contractual obligations for performance.
- e. Principal Investigators and Project Directors do not have authority to make (execute) changes or modifications in the terms of contracts or grants.
- f. Only the President/Executive Director may make changes.
- g. PI's should not attempt to negotiate such changes without the prior knowledge and approval of the Executive Director.
- h. The person(s) named in the award of a contract or grant accepted by EBIRE as the Principal Investigator has primary responsibility for adherence to the terms and conditions of the award and for ensuring that expenditures made are appropriate, allowable, and within the budgetary limitations of the contract or grant.

#### **17. Administrative Overhead Fee**

Each research activity shall include an Administrative Overhead Fee (aka Indirect Cost Rate) which is up to 24% for EBIRE. For Federally funded grants, the Indirect Cost Rate will be that which is negotiated with the funding agency or with Department of Health and Human Services.

All Administrative Overhead Fees/Indirect Cost Rates shall be available as EBIRE operating funds.

- a. For federal support, EBIRE annually negotiates an F&A rate with the Department of Health & Human Services, the cognizant federal agency.

#### **18. Regulatory Compliance Monitoring**

It is the intent that EBIRE not only administer research contracts and related funds, but also provide real-time support to PIs and their staff as to regulatory compliance. Note that nothing in this document is intended to replace pre-existing SOPs administered by VANCHCS and its compliance requirements.

##### **a. MINIMUM REGULATORY DOCUMENTATION**

##### **i. Study Approval Documents**

1. Initial approval actions
2. Initial Submission to IRB
3. R&DC approval letter or notification signed by ACOS

4. IRB approval letter
- ii. Continuing Approval Actions
  1. IRB approval letter
  2. R&DC approval letter or notification signed by ACOS
- iii. Amendments
  1. Amendment documents
  2. IRB approval letter documenting any specific approved protocol changes
- iv. Other Actions: Requests for Study closure
- v. Qualifications and Training
  1. Training Records for all research team members (Only Research Service required training)
  2. Scope of Practice for each member of the Project
- vi. Study Conduct Documents
  1. Copy of Protocol (all versions)
  2. Informed Consent (all versions stamped and approved)
  3. HIPAA Authorizations (all versions stamped and approved)
  4. Any advertisements, questionnaires, telephone recruitment scripts, screening forms which state inclusion/exclusion criteria
  5. Subcommittee on Research Safety (SRS) Forms including all approval documents
- vii. Subject Records
  1. Enrollment logs (Master list of subjects)
  2. Dates of consent
  3. Signed Informed consent documents
  4. Signed HIPAA Authorizations
  5. Any documentation that Inclusion/Exclusion criteria was met
  6. Any Source documentation (e.g. laboratory results, CPRS and clinician notes)
  7. Any correspondence with sponsor, or any related "Notes to File"
- viii. Safety Reports
  1. Local Serious Adverse Events reported to the IRB
  2. Any IRB correspondence acknowledging receipt of adverse event report
  3. Any IRB correspondence documenting IRB actions concerning the adverse event

ix. Study Closure Documentation if the Study is Being Closed

1. Any documentation provided by the sponsor involving closure
2. Any documentation sent back to sponsor involving closure
3. Any documentation transacted between PI and VANCHCS IRB involving closure
4. Any documentation sent to current or prospective subjects involving closure
5. All documentation involved with the actual closure of study

**b. PROJECT-SPECIFIC RECORDKEEPING**

i. Physical Records

1. Before a project administered by EBIRE is initiated, EBIRE will provide the PI and/or their designated research coordinator a physical and electronic copy of this policy, as well as supplies needed to prepare a physical system for collecting and storing all regulatory documents.
2. PI and/or their designated research coordinator shall maintain physical copies of all study-related information.
  1. All physical copies must be kept together in an organized manner, and satisfactorily secured. Examples of 'satisfactorily secured' includes, but is not necessarily limited to:
    - ✓ Storage box at the coordinator's desk, which is in an office that is locked when not in use
    - ✓ Drawer of coordinator's desk, which is locked when not in use
    - ✓ File cabinet that housed in an 'employee only' part of a clinic.

**19. Intergovernmental Personnel Act (IPA)**

IPAs are agreements pursuant to the Intergovernmental Act which provides a mechanism for the Federal government to share staff across institutional boundaries. At the VANCHCS, IPAs may be implemented in two situations:

- a. To allocate EBIRE or UC Davis employees to intramural (VA-funded) projects; or
- b. To allocate VA employees to extramural (EBIRE-administered or UC Davis-funded) projects.

The IPA mechanism may **NOT** be used under the following circumstances:

- For an employee who has been an EBIRE employee for less than 90 days
- For an employee serving in administrative or clinical functions
- For a temporary employee, including post-docs and others in training positions (and in the case of a VA employee, those with a time-limited appointment)
- For more than two years without amendment, or for a total of four years without a break in service of 60 days
- In the case of a VA employee, for a lifetime total of more than six years

Other rules established by the federal Office of Personnel Management or by VA, may apply.

EBIRE charges a fee for processing and maintaining IPAs to offset associated Human Resources and other administrative costs. The fee is 10% of the salary and benefit cost of the IPA, not to exceed a predetermined maximum per fiscal year and must be funded through unrestricted sources.

To initiate an IPA agreement:

- i. The IPA forms and processes utilized by the VANCHCS Research Service shall be used;
- ii. IPA questionnaires must be completed a minimum of two weeks prior to the effective date to assure seamless implementation at the desired IPA start date;
- iii. All VA compliance requirements must be met prior to IPA start date and activations. This includes:
  1. The WOC appointment must cover the entire IPA appointment period.
    - a. If the WOC is scheduled to expire prior to the IPA appointment period, either the IPA or the WOC appointment must be adjusted.
  2. At least annually, confirmation that EBIRE is a member of NAVREF (National Association of Veterans' Research and Education Foundations) **AND** the VANCHCS Research Service has delegated authority to initiate IPA's from the Chief Research and Development Officer.
- iv. For EBIRE employees covered under an IPA, the IPA start date must coincide with the start of an EBIRE pay period, i.e. the 1<sup>st</sup> or 16<sup>th</sup> of the month.

## 20. Educational Activities

The VANCHCS supports the ongoing development of its faculty and staff through educational activities designed to increase the breadth of knowledge used to facilitate patient care. EBIRE is committed to facilitating such activities so that three (3) major goals are achieved:

- i. Improving current job performance.
- ii. Maintaining and/or enhancing employee specialized proficiencies.
- iii. Expanding the knowledge pertaining to advances and changes in patient care, technology and health care administration.

The following procedures apply to educational funds:

1. All educational programs, sessions, and meeting must be approved by the Education Committee.
2. All educational donations must include a letter from the sponsor, which designates the funds as an educational donation.
3. All funds must be made payable to EBIRE.

4. If the sponsor is a public entity, the donation letter must be on the organization's or agency's letterhead.
5. EBIRE's indirect rate will be either 9% or 11%, depending on the effort involved with administering the activity.

## **21. Research Agreements & Project Initiation**

- i. Animal and Laboratory Studies: Research agreements with sponsors must be submitted for review to the Executive Director.
- ii. Clinical Trials: Effective March 15, 2006, the VA's Clinical Trial Cooperative Research and Development Agreement (CT CRADA) template will be used during negotiations with collaborators for clinical trials conducted at the VANCHCS.

The Investigator should not sign nor finalize negotiations on any portion of the agreement until concurrence is achieved by all parties.

The following information will be needed for each agreement:

**Sponsor's Name**

**Business Address**

**Contact Person**

**Telephone and Fax Numbers**

**E-Mail Address**

**Title of Study/Project**

**Copy of Study Budget (must include EBIRE overhead fees)**

If the study/project involves human subjects, the Investigator is required to provide EBIRE with a completed Assessment of Clinical Impact Form, which outlines the obligations of the study to the VANCHCS.

Prior to initiating an EBIRE administered study/project or accepting project related funds, the following criteria must be met:

1. Prior written approval by VA Office of General Counsel (VA OGC) of the proposed agreement in the event of a Cooperative Research and Education Agreement (CRADA).
2. VA Research & Development Committee and sub-committee (IRB, IACUC) approval.
3. Fully executed agreement between EBIRE and the project's sponsor.

## **22. Clinical Trial Budget Review**

Budgets associated with clinical trial studies must be submitted to EBIRE for review and approval as part of the clinical trial agreement concurrence.

The Principal Investigator and/or Clinical Coordinator must schedule an appointment with the EBIRE Executive Director to review the protocol and the medical procedures involved in conducting the study. This is completed to determine procedures considered above the standard of care and reimbursement of costs to the VANCHCS.

Please provide the following information which will be discussed during the meeting:

1. Completed Assessment of Clinical Impact Form
2. Listing of Procedures Involved (including CPT codes)

### **23. Research Funds & Equipment**

EBIRE and all other VA-affiliated Nonprofit Corporations established under 38 U.S.C. Sections 7361-7366 have as their purpose the facilitation of VA research and education. EBIRE has no authority to accept or administer funds for research other than VA research. Once funds and research equipment are transferred to a VA affiliated nonprofit such as EBIRE those resources (with the exception of EBIRE overhead deductions) are VA research property. These resources do not belong to an investigator. These accounts are maintained for residual funds using the researcher's name as a place holder for administrative convenience. The investigators perform VA research as VA employees. They are not parties to research agreements and the money is not assigned to the researcher him or herself. The funds are VA money.

### **24. Project Close-out Procedures & Reserve Funds**

When a project is finalized or terminated, it must be closed with the VA Research & Development Office and EBIRE. Investigators should follow these steps to move any funds to an unrestricted account:

1. Close the project with the VA R&D Office and ensure that the project is terminated or finalized.
2. If the project is a clinical trial, complete the Clinical Trial Closeout Checklist.
3. Provide the EBIRE Executive Director with any pending bills or commitments.
4. Certify that VA has been reimbursed for any ancillary tests above the standard of care.
5. Certify that no funds are due the sponsor.

Any remaining funds may then be transferred to an unrestricted account pursuant to section 21 above.

### **25. Project Transfers of Equipment & Funds**

1. **Transfers:** If the Principal Investigator transfers to another VA location and wishes to move the research project to another nonprofit tax-exempt entity (University or VA affiliated NPC), a letter must be received by the EBIRE Executive Director from

the new corporation requesting the transfer and advising that they will accept responsibility for the research project, funds and equipment.

- a. Any and all transfers of funds or equipment out of EBIRE, regardless of amount, must be approved by the EBIRE Board of Directors.
  - b. When a Principal Investigator leaves VA, becomes employed by a for-profit organization, or retires, the distribution of any and all remaining project funds and equipment will be determined by the EBIRE Board of Directors.
2. **Equipment:** All equipment and funds remain with EBIRE until the EBIRE Board determines their appropriate disposition.
- a. Transfer of funds and/or equipment may only be made to another nonprofit entity and must benefit VA research or education.
  - b. The Principal Investigator is responsible for the shipment of any equipment to the new nonprofit corporation.
  - c. Sales of any equipment must be approved by the Board of Directors.
  - d. Proceeds from any sales will be deposited to EBIRE's corporate operating fund.
  - e. With the approval of the EBIRE Executive Director, any equipment purchased by EBIRE may be loaned to a Principal Investigator or another entity, to be housed at an off-site location if it is in support of the VANCHCS research project. Loans must be documented in the EBIRE accounting system and renewed and approved on an annual basis. When the loan period is complete, the individual or entity having possession of the equipment may request an extension or must return the equipment to EBIRE.

Accounts established to support research and development and education are ultimately the responsibility of the Board of Directors. In an effort to maximize usage and to ensure that we meet the highest accounting standards, investigators/fund holders are expected to utilize accounts for the purposes indicated by the donor, sponsor or grantor.

Any funds or equipment remaining after completion of a research project or educational activity that the sponsor does not require to be returned (residual funds) will be used for the general support of VA research, VA education, or for EBIRE consistent with the requirements of VHA Handbook 1200.17 and the residual fund policy of EBIRE.

## **26. Authorized Signers**

Only the Executive Director will sign contracts and agreements for EBIRE, including purchase orders and CRADAs. The Executive Director will only sign CRADA's after they have been reviewed and approved in writing by the VA Regional Counsel.

## **27. Reimbursements Policy**

The Request for Reimbursement form may be used for reimbursements to individuals for expenditures made for small supplies necessary for a particular project. These expenditures should not be in excess of \$100 and all original receipts must be attached to the Request for Reimbursement Form.

If it is more practical to make a purchase with an individual's credit card and the amount will be over \$50, a Purchase Request Form must be prepared and approved before making the purchase. The related PO number should then be entered on the "Request for Reimbursement" form.

## **28. Subscriptions & Memberships Policy**

Expenditures for continued education, including scientific books, conference and registration fees, society memberships, etc., that facilitate the VA's research and education missions may be requested by submitting a Purchase Request form. Subscriptions or professional association dues, with the exception of license fees, may be paid from appropriate research or general operating funds upon approval by the EBIRE Executive Director. All subscriptions must be addressed to a VA address.

Everything paid for by EBIRE on behalf of an investigator must support approved VA research or VA education activities.

Organizational memberships cannot be paid for by EBIRE unless the membership is necessary in order to receive the organization's journal or publications.

The investigator must explain on the Purchase Request Form exactly how the particular publication or subscription is needed for the specific research project.

## **29. Study Subject Payment Guidelines**

Principal Investigators requesting payment to a study subject for their participation in research activities must submit the name, mailing address and social security number for each subject. In any case where any study subject received in total \$600 or more in a calendar year, EBIRE must submit such year-end information to the IRS and to the study subject on IRS Form 1099.

Below are three related forms to be used when making payments to any person or institute related to study subject/patient participation in the research project:

- i. Reimbursement of VAMC cost is used to reimburse the Medical Center for patient care costs incurred specifically for the research project, such as Inpatient Medicine, Outpatient Services, etc. using rates agreed upon by the VA and EBIRE.



- ii. Patient per diem payments are used to pay the subject/patient for any agreed upon per diem payment for participation in the study.
- iii. A standard Study Subject/Patient Payment Form will be used to pay the subject/patient for any agreed upon payment for his/her total participation in the study.

### **30. Consultant Services**

A consultant is an individual that has been contracted to complete a specific and necessary aspect of an authorized project with definitive closure, i.e. such as a report, or data collected for a specified number of patients. When retaining an individual's services, a contract must be completed between the consultant and the PI. This contract must be submitted to the EBIRE Executive Director for approval before work can begin.

### **31. Independent Contractor Information**

An individual may only be retained for personal or professional services as an independent contractor if a determination has been made that an employer-employee relationship does not exist. Please refer to the IRS website for specific instructions.

### **32. Intermittent Employees**

An intermittent employee is one that is hired to work on an "as needed" basis with no set tour of duty. An intermittent employee is not eligible for any benefits that EBIRE offers.

### **33. Receipts of Honoraria**

EBIRE will not accept honoraria provided to an investigator as payment for participation in an activity.

### **34. Payments of Honoraria**

EBIRE will pay honoraria as requested to support a research or educational activity. The following criteria must be met:

1. The payment must be properly requested in advance and approved by the EBIRE Executive Director in advance.
2. The honorarium requested is of a reasonable, nominal amount.
3. The recipient of the honorarium is not a Federal employee.

### **35. Study Subject Payments**

PIs requesting payment to a study subject for their participation in research projects must submit the name, mailing address and social security number for each subject.

In any case where any subject receives in total \$600 or more in a calendar year, the EBIRE must submit such year-end information on Form 1099 to the IRS and to the study subject.

## **VI. Insurance**

EBIRE will obtain and keep in effect adequate directors and officers (“D&O”) insurance, general liability insurance, and theft and embezzlement insurance. The Board will review EBIRE’s insurance coverage annually to ensure (1) limits are adequate, and (2) EBIRE has insurance coverage appropriate for its activities.

## **VII. Disaster Plan & Continuity of Operations**

The EBIRE Executive Director will develop a disaster plan to provide for continued operations and have it approved by the Board. This should be updated every two-three years.

## **VIII. Whistleblower Procedures**

EBIRE employees or those working on behalf of EBIRE should report observed, suspected or apparent misconduct to the VANCHCS Medical Center Director (hereafter referred to as the “Officer”). If an individual is unsure whether a suspected incident falls within the definition of misconduct, he or she may contact the Officer to discuss the suspected misconduct informally. If the circumstances described by the individual do not meet the definition scientific misconduct, the Officer will refer the individual or allegation to other offices or officials with responsibility for resolving the problem.

At any time, personnel may have confidential discussions and consultations about concerns of possible misconduct with the Executive Director or the Officer and will be counseled about appropriate procedures for reporting allegations.

Any formal allegation of misconduct that is received by an EBIRE member, officer or employee must be referred to the Officer.

The Officer will monitor the treatment of individuals who bring allegations of misconduct or of inadequate institutional response thereto, and those who cooperate in good faith with inquiries or investigations. The Officer will ensure that these persons will not be retaliated against in the terms and conditions of their employment or other status and will review instances of alleged retaliation for appropriate action. Personnel should immediately report any alleged or apparent retaliation to the Officer.

EBIRE will also protect the privacy of those who report misconduct in good faith to the maximum extent possible.

## **IX. Records Retention**

It is the policy of the East Bay Institute for Research & Education to comply with all federal and state laws regarding the retention of company records as well as the destruction of such records when the obligation for retaining them has expired.

All stored records will be marked with the appropriate designation and destruction date. Upon reaching that destruction date, the EBIRE Records Management Designee (appointed by the President/ED) will initiate appropriate action for the destruction of documents. Records maintained by EBIRE shall be destroyed by EBIRE; records maintained by VANCHCS shall be stored and destroyed by the VANCHCS Records Manager.

EBIRE shall coordinate records retention efforts according to the following categories and retention periods:

***EBIRE Corporate Records***, to be maintained ***by EBIRE*** according to the following schedule:

<b>Document Type</b>	<b>Retention Period</b>
Incorporation records	Permanent
Meeting Minutes	Permanent
Board Member Compliance	Permanent
Physical inventory records	7 years
Tax returns & worksheets	Permanent

***Financial Records***, to be maintained ***by EBIRE*** according to the following schedule:

<b>Document Type</b>	<b>Retention Period</b>
<b>Accounting and Finance</b>	
Accounts Payable	7 years
Accounts Receivable	7 years
Annual Financial Statements and Audit Reports	Permanent
Bank Statements, Reconciliations and Deposit Slips	7 years
Canceled Checks - routine	7 years
Canceled Checks - special (such as loan repayment)	Permanent
Credit Card Receipts	3 years
Donations	7 years
Employee/Business Expense Reports/Documents	7 years
General Ledger	Permanent
Insurance records	7 years
Interim Financial Statements	7 years

***Personnel Records***, to be maintained ***by EBIRE*** according to the following schedule:

<b>Document Type</b>	<b>Retention Period</b>
Accident reports and claims (employment-related)	7 years
Employment applications	2 years
EEOC reports	7 years
Garnishments	7 years
I-9's	1 year after termination
Payroll records	Permanent
Personnel files (terminated)	7 years after termination
Pension plan records	Permanent
Workers Compensation documents	2 years after termination

Grant-Funded Protocol Records, to be maintained by VANCHCS according to the following schedule:

Document Type	Retention Period
<p><b>NOTE:</b> See also SECTION XLVII - OFFICE OF RESEARCH OVERSIGHT, VHA Records Control Schedule 10-1.</p> <p>Records to be processed by VANCHCS shall be handled as follows:</p> <ul style="list-style-type: none"> <li>▪ VA related Research documents will be packed using the standard records boxes Per VA HANDBOOK 6300.1, MARCH 24, 2010</li> <li>▪ All non-record material and extra copies will be removed.</li> <li>▪ Records will be separated into series, defined as a "block of records having the same disposition authority and same disposition date."</li> <li>▪ Each item or subordinate item in the records control schedule represents a series.</li> <li>▪ Records will be identified and sorted into blocks (series) by item number and cut-off date.</li> <li>▪ Upon being appropriately boxed, EBIRE Records Management Designee will contact VANCHCS Records Manager. <ul style="list-style-type: none"> <li>○ VANCHCS Records Manager will prepare and send to a NARA approved center.</li> <li>○ Each series of records must be transferred as a separate accession.</li> <li>○ Mixed series cannot be accepted.</li> </ul> </li> <li>▪ Records whose disposal date has passed must not be sent to a NARA records storage facility. <ul style="list-style-type: none"> <li>○ Such records must be disposed of locally.</li> </ul> </li> </ul>	
Grants (Unfunded)	2 years
NIH Grants	3 years from close of project
Other Federally or Foundation funded grants	As determined by funder, but no less than 3 years from close of project
Industry-sponsored projects	7 years from close of project
Research Misconduct Investigation records	7 years from case closure

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## **X. Computer & Other Security**

General office security is maintained during normal business hours. After hours, all doors are locked and all computer workstations are also locked.

All EBIRE files, blank check stock, and other records are stored in a fireproof file cabinet in the office. This cabinet is locked each night and the key is secured.

EBIRE will permit only duly authorized personnel with data input and reporting responsibilities access to the QuickBooks accounting software and data.

The VA IT system for the VANCHCS will be utilized for all of EBIRE's IT operations.

## **XI. Accounting Practices**

### **Financial Statements**

EBIRE will utilize financial statements on a cash-basis in accordance with generally accepted accounting principles applicable in the U.S. EBIRE's fiscal year shall be October 1 to September 30. At the end of the fiscal year, all accounts/funds must be reviewed and preliminary financial reports prepared. If an audit by an outside independent auditor is required under the provisions of VHA Handbook 1200.17, then arrangements will be made to have the year-end financial statements audited.

EBIRE's basic financial statements will include:

1. Balance Sheet
2. Profit & Loss Statement
3. Budget Report with YTD and Prior Year
4. Summary Narrative on Results of Operations and Financial Position

The objective is to prepare accurate financial statements in accordance with generally accepted accounting principles and distribute them in a timely manner. In meeting this responsibility, a standard set of financial statements will be produced on a monthly basis.

The EBIRE Executive Director will distribute a complete set of quarterly financial statements, with additional supplemental schedules to provide explanations for material budget variances in accordance with the established budget monitoring procedures, to all Board Members in advance of each quarterly board meeting.

## **Operating Budget**

The Board annually approves an operating budget for EBIRE. In addition, the Board reviews the financial statements quarterly.

The Board will review and approve the EBIRE's financial and operating policies.

1. Preparing financial statements and communicating key financial information is a necessary and critical accounting function.
  - i. Financial statements are management tools used in making decisions, in monitoring the achievement of financial objectives, and as a standard method for providing information to interested parties external to EBIRE.
  - ii. Wherever possible, financial statements should reflect year-to-year historical comparisons and/or current year budget to actual comparisons.
2. A budget will be prepared by the Executive Director to direct the most efficient and prudent use of EBIRE's financial resources.
  - i. A budget is a management commitment of a plan for present and future corporate activities that will help ensure economic survival and prosperity.
  - ii. The budget will be presented annually to the Board of Directors for adoption.
  - iii. It is EBIRE's policy to monitor its financial performance by comparing and analyzing actual results with budgeted results.
  - iv. This function shall be accomplished in conjunction with the quarterly financial reports at the quarterly Board meetings.
  - v. Financial reports comparing actual year-to-date revenues and expenses with budgeted year-to-date amounts will be distributed to the Board.
  - vi. All significant budget variances will be explained in writing to the Board.

## **Budget Modification**

The Executive Director must approve any reclassification of budget expenses. All budget revisions must be reviewed and approved by the Board of Directors.

## **Audits**

If EBIRE has annual revenues between \$100,000 and \$500,000 an audit will be obtained at least every three years. EBIRE will obtain an annual independent audit in compliance with OMB Circular rules. The Board of Directors is responsible for selecting an independent auditor. After the conclusion of the audit, the Board must meet with the outside auditor independent of staff. The Board may elect to establish an Audit Committee to arrange for the outside audit and receive the auditors' report.

## **Internal Accounting Control System**

The safeguarding of assets and the reliability of financial records are the primary objectives for EBIRE's internal accounting controls.

An organizational chart that clearly defines the organization's activities by function shall be established and maintained. A system of controls over revenues and expenses, including comparisons with approved budget estimates shall be established and maintained.

## **Utilization of Funds**

### **Payments By Check:**

EBIRE checks are to be signed by two of the designated and authorized signers.

1. **Administrative Expenses:** All EBIRE expenditures must be limited to those that further EBIRE's purposes. This includes expenditures for equipment and supplies, personnel, subscriptions, education, travel and entertainment.
2. **Research Accounts:** EBIRE may create a research account in conjunction with a specific research project.
  - i. Distribution of funds will be from the appropriate research account.
  - ii. All requests for expenditures must be made and approved by the Principal Investigator or designee.
  - iii. If the Executive Director reviews a proposed expenditure and deems it inappropriate, the Principal Investigator may seek review by the Board of Directors for final disposition.
  - iv. Note that disapproved requests will be retained in EBIRE's files as evidence of review and disapproval for future audits.

### **Payments By EBIRE Credit Card:**

EBIRE shall have one credit card, in the name of the President/Executive Director, for purchases that require payment via credit. This type of payment shall be limited to only such expenditures that require payment via credit card, e.g. travel, online training registration. Credit purchases are only to be made when there are undesignated funds available to pay off the entire credit balance; EBIRE shall not ever carry an ongoing credit debt on a credit card, as this would be an unreasonable use of the Institute's financial resources.

### **Payments By Wire Transfers:**

Two Board Members with signatory authority on the bank account must authorize any funds that are transferred out of EBIRE's account by wire.



### **Check Preparation & Electronic Expenditures:**

Expenditures must be supported with adequate documentation and be in conformity with EBIRE's policies and procedures. Timing of disbursements should generally be made to take advantage of all early payment discounts that may be offered by vendors.

It is EBIRE's intent to pay vendors within 30 days of submitting a proper invoice upon delivery, complete and in good condition, of the requested goods or services. To accomplish this, the following steps shall be followed:

1. Total cash requirements associated with each written check/electronic expenditure will be monitored in conjunction with available cash balance in the bank prior to release of any checks.
2. All supporting documentation is attached to the corresponding check or electronic expenditure prior to forwarding the entire package to an authorized signatory.
3. Checks will be utilized in numerical order, whenever possible.
4. Checks will never be made payable to "cash."
5. Checks will never be signed prior to being prepared.
6. All checks received by EBIRE must be recorded into a ledger maintained in the QuickBooks accounting system.

### **Deposit of Funds**

All checks received are to be restrictively endorsed upon receipt deposited to the bank as soon as possible.

### **Financial Loans**

No loans or advances will be made for any purpose without prior written Board approval.

### **Investments**

EBIRE funds may only be invested with approval of the Board of Directors. EBIRE will minimize the risk to principal in every investment strategy. Investment in stocks, mutual funds, federal agencies, or similar investment vehicles is prohibited. Funds should be deposited in interest bearing accounts that are Federally-approved depositories, such as Federally insured banks, savings and loans, or credit unions. Money Market accounts qualify if they are Federally insured. EBIRE funds may be placed in insured accounts, certificates of deposit, or other investments guaranteed by the U.S. Government against risk of loss through the Federal Depository Insurance Corporation (FDIC) or the National Credit Union Association (NCUA, a Federal Agency).

### **Voided Checks**

Checks may be voided due to processing errors by making proper notations in the check register and clearly marking the check VOID. All voided checks are retained in a checks file.

## **Bank Account Reconciliation**

Bank account statements are received each month and initially reviewed by the Executive Director, then forwarded to the designated bookkeeper. The designated bookkeeper will prepare a formal reconciliation between bank balance and general ledger balance, for presentation to the Executive Director and Board of Directors quarterly. The monthly bank reconciliation will be completed within the following month. Bank reconciliations are filed in the current year's accounting files.

## **Signature Stamp**

Whenever possible signature stamps will not be used. All checks and documents will be manually signed.

## **QuickBooks**

EBIRE will use the QuickBooks system to track all financial activities. This system will be established with the following criteria:

### General Ledger and Chart of Accounts

The general ledger is defined as a group of accounts that supports the information shown in the major financial statements. The general ledger is used to accumulate all financial transactions of EBIRE, and is supported by subsidiary ledgers that provide details for certain accounts in the general ledger. The general ledger is the foundation for the accumulation of data and reports.

### Chart of Accounts Overview

The chart of accounts is the framework for the general ledger system, and therefore the basis for EBIRE's accounting system. The chart of accounts consists of account titles and account numbers assigned to the titles. General ledger accounts are used to accumulate transactions and the impact of these transactions on each asset, liability, net asset, revenue, expense and gain and loss account.

EBIRE's chart of accounts is comprised of six types of accounts:

1. Assets
2. Liabilities
3. Net Assets
4. Revenues
5. Expenses
6. Other Revenues and Expenses

There are two types of accounts: real accounts and nominal accounts. Real accounts are asset, liability, and net asset accounts and they appear on the statement of financial position. Nominal or temporary accounts are revenue and expense accounts, as well as gain and loss accounts, and they appear on the statement of activities. EBIRE's nominal accounts are annually closed or zeroed out, but real accounts are permanent.

A two-digit type number and a four-digit classification code shall precede each account number.

### Distribution of Chart of Accounts

All EBIRE's employees involved with account coding responsibilities (assignment or review of coding) or budgetary responsibilities will be issued a current chart of accounts. As the chart of accounts is revised, an updated copy of the chart of accounts shall be distributed to these individuals promptly.

### Control of Chart of Accounts

EBIRE's chart of accounts is monitored and controlled by the Executive Director.

Responsibilities include the handling of all account maintenance, such as additions and deletions. Any additions or deletions of accounts should be approved by the Executive Director, who ensures that the chart of accounts is consistent with the Corporate structure of EBIRE and meets the needs of each division and department.

### Account Definitions

#### General Ledger

#### Account Range

1000 - 1999

#### Category

**Assets**

#### Definition

Assets are probable future economic benefits obtained or controlled by the Corporation as a result of past transactions or events. Assets of Example NPO are classified as current assets, fixed assets, contra-assets, and other assets.

Current Assets are assets that are available or can be made readily available to meet the cost of operations or to pay current liabilities. Some examples are cash, temporary investments, and receivables that will be collected within one year of the statement of financial position date.

Fixed Assets are tangible assets with a useful life of more than one year that are acquired for use in the operation of the Corporation and are not held for resale.

Contra-Assets are accounts that reduce asset accounts, such as accumulated depreciation and reserves for uncollectible accounts receivable

Other Assets include long-term assets that are assets acquired without the intention of disposing them in the near future. Some examples are security deposits, property and long-term investments.

2000 - 2999

#### **Liabilities**

Liabilities are probable future sacrifices of economic benefits arising from present obligations of the Corporation to transfer assets or provide services to other entities in the future as a result of past transactions or events. Liabilities of EBIRE are classified as current or long-term.

Current Liabilities are probable sacrifices of economic benefits that will likely occur within one year of the date of the financial statements or which have a due date of one year or less. Common examples of current liabilities include accounts payable, accrued liabilities, short-term notes payable, and deferred revenue.

Long-Term Liabilities are probable sacrifices of economic benefits that will likely occur more than one year from the date of the financial statements. An example is the non-current portion of a mortgage loan.

3000 - 3999	<b>Net Assets</b>	<u>Net Assets</u> is the difference between total assets and total liabilities. See the next section for EBIRE's policies on classifying net assets.
4000 - 4999	<b>Revenues</b>	<u>Revenue</u> is inflows or other enhancements of assets, or settlements of liabilities, from delivering or producing goods, rendering services, or other activities that constitute an Corporation's ongoing major or central operations. Revenues of EBIRE include membership dues, conference registrations, and sales of publications. Also included in revenues of EBIRE are contributions received from donors.
6000 - 7999	<b>Expenses</b>	<u>Expense</u> is outflows or other using up of assets or incurrences of liabilities from delivering or producing goods, rendering services, or carrying out other activities that constitute EBIRE's ongoing major or central operations.
8000 - 8999	<b>Other Revenue &amp; Expenses</b>	<u>Gains</u> are increases in net assets from peripheral or incidental transactions and from all other transactions and other events and circumstances affecting the Corporation except those that result from revenues or contributions.  <u>Losses</u> are decreases in net assets from peripheral or incidental transactions and from all other transactions and other events and circumstances affecting the Corporation except those that result from expenses. Gains or losses occur when EBIRE sells a fixed asset or writes off as worthless a fixed asset with remaining book value.

### **Classification of Net Assets**

Net assets of the Corporation shall be classified based upon the existence or absence of donor-imposed restrictions as follows:

**Unrestricted Net Assets** - Net assets that are not subject to donor imposed stipulations.

**Temporarily Restricted Net Assets** - Net assets subject to donor imposed stipulations that may or will be satisfied through the actions of EBIRE and/or the passage of time.

**Restricted Net Assets** - Net assets subject to donor imposed stipulations that EBIRE permanently maintain certain contributed assets. Generally, donors of such assets permit EBIRE to use all or part of the income earned from permanently restricted net assets for general operations or for specific purposes.

Net assets accumulated by EBIRE that are not subject to donor imposed restrictions, but which the board of directors of EBIRE has earmarked for specific uses, shall be segregated in the accounting records as "board-designated" funds within the unrestricted category of net assets.

### **Changes to the Chart of Accounts**

Additions to, deletions from, or any other changes to EBIRE's standard chart of accounts shall only be done with the approval of the Executive Director.

### **Sources and Management of Funds:**

EBIRE may accept funds in the form of grants, agreements or gifts from such sources as: federal, state, or nonprofit agencies; commercial organizations involved in the development of new medical materials and devices or in support of medical research and/or education; personal contributions; or from organizations or individuals to defray the costs of scientific meetings, teaching or other legitimate academic functions. EBIRE may administer government grants and contracts. Funds donated in support of a research project can be accepted only if the Principal Investigator holds an appointment at the VANCHCS. All checks must be made payable to East Bay Institute for Research and Education. If a donor letter does not accompany the funds, EBIRE will send an acknowledgement letter that outlines the intended use for the funds. A sample of this letter is attached.

Funds donated in support of an educational activity can be accepted and expended according to the funders' requirements. When applicable, approval of the VANCHCS Education Committee will be obtained.

Funds received for specific projects or activities may be co-mingled in the same bank account with other grants and donations. However, separate project accounting for the funds must be maintained.

### **Ownership of Funds:**

All funds accepted by EBIRE represent corporate income and are not to be used for the personal benefit of any investigator or other individuals. All interest income earned remains entirely with the corporation.

- i. Money maintained in research accounts in the name of individual investigators is nonetheless EBIRE's sole property.
- ii. If an investigator subsequently does not qualify as a VA investigator, or resigns, all

unrestricted funds remaining after outstanding obligations have been met will remain with EBIRE.

**Meal Expenses:**

EBIRE's research funds may be used for reasonable business-related meals, e.g. recruitment dinner for a visiting physician or scientist.

- i. Such expenses are to be charged against the appropriate research activity account.
- ii. EBIRE operating funds may also be used for reasonable business-related meals if the primary purpose of the expense is related to furthering EBIRE's mission and/or the research activities at the VANCHCS.

In the case of expenses, the following elements must be carefully documented:

- i. The amount of each separate expense.
- ii. The date the meal took place.
- iii. The reason for the meal, or the nature of the business benefit expected to be derived, and the nature of the business discussion or activity that took place.
- iv. The occupation or other information relative to the person or persons entertained, including name, title or other designation, sufficient to establish a business relationship to EBIRE and to VA.

**Reimbursement of VA Services:**

Specific medical center costs incurred for clinical/diagnostic/support services provided solely for the purpose of obtaining data on patients in a funded research study, exclusive of routine patient care, should be reimbursed to VA.

- 1. Such reimbursements should be made from the appropriate research activity account. Reimbursable services may include, but are not limited to: radiology, laboratory, pharmacy, and specific sections of medicine.
- 2. Projected medical center costs that may be generated beyond normal patient care are to be budgeted by the Principal Investigator and reserved for payments against of bills of collection from VA.

**Purchasing**

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 request form to the Executive Director.

- a. All purchase requests must be submitted using EBIRE's standard purchase request forms, not VA forms.

- b. The Executive Director will review the requests for appropriateness and to ensure all parts of the requisition are completed properly.
- i. EBIRE is not exempt from sales and excise taxes. We must pay tax on all tangible goods purchased for use in California. If sales tax is not charged, EBIRE is required to pay use tax to the state.
  - ii. There must be a Signature Authority Delegation on file for anyone other than the Principal Investigator to approve expenditures. Signature stamps are not acceptable.
  - iii. All goods and services must have a research or education relation. Additionally, project, activity or program specific expenses require Research & Development Committee or Education Committee approval of the associated project, activity or program.
  - iv. Purchases considered to provide predominantly personal benefit are not allowed.
  - v. EBIRE does not provide discretionary spending accounts or tax indemnification and gross up payments.
  - vi. No expenditure will be authorized for personal housing expenses, business use of personal residence, health or social club dues or initiation fees, or personal services (e.g., maid, chauffeur).
  - vii. Expenses related to professional licensure (annual fees, Board certification courses, etc.) are not allowable, regardless of source of support.
  - viii. No purchase which may result in the appearance of a conflict of interest will be made.
  - ix. No expenditure will be authorized for memberships with EBIRE funds unless it includes a publication which furthers the VA's research or education mission.
  - x. No expenditures will be authorized for donations.
  - xi. No expenditures will be authorized for lobbying or political activities.
  - xii. EBIRE is not responsible for upgrade, repair or maintenance of VA or University Affiliate owned equipment. However, if such are allowable and appropriate, EBIRE funds may be used for such support.
  - xiii. Business meetings may be appropriate for EBIRE support. If there is any question about what will or will not be allowed, pre-approval is strongly

suggested. This approval can be obtained by email with EBIRE Administration.

- xiv. A test of reasonableness will prevail in any acquisition for goods or services, including personal services, supported by EBIRE.
- c. The Executive Director will then approve, by signing and dating, the purchase requests.
- d. The Executive Director or designee will order all items.
- e. The Principal Investigator or designee will inspect orders upon receipt and return signed and dated packing slips to the Executive Director or designee as verification of receipt.

All expenditures regardless of amount must be approved by the Executive Director as well as the Principal Investigator.

Any item over \$10,000 must have at least three competitive bids unless sole source justification can be provided. Orders may not be split to avoid abiding by this policy.

### **Purchase Orders**

EBIRE will use their internally-developed Purchase Order ("PO") request form. The form has a series of boxes that must be completed, among which are:

- i. PO date (date of request)
- ii. Requester or Principal Investigator
- iii. Project number (specify account)
- iv. Description
- v. Proposed sourcing
- vi. Quoted price
- vii. Executive Director's signature

### **Equipment Inventory/Limitations**

Equipment is any tangible asset having a useful life of at least one year and that may be depreciated.

All corporate purchased equipment is to be physically inventoried at least annually, evaluated for impairment, and reconciled to the general ledger.



Detailed records of equipment purchased with EBIRE funds will be kept and the equipment must be tagged with an EBIRE property tag and registered with the Acquisitions and Material Service as non-government equipment on loan to VA.

The Board of Directors must approve the transfer or sale of all corporate-purchased equipment. Should a Principal Investigator want to transfer equipment to another not-for-profit institution, a written request must be submitted to the Board. No equipment may be transferred to a for-profit institution. Correspondence to and acknowledgement from the receiving entity should be retained in EBIRE's files for documentation. EBIRE will retain physical possession of all equipment until such time that it is donated to VA or otherwise distributed to an appropriate individual or entity.

All EBIRE equipment must be maintained using EBIRE funds. EBIRE funds may be used to repair VA equipment if the PI/Member has no VA funds but continues to use VA equipment in support of approved research funded through EBIRE.

EBIRE funds may not be used to purchase or repair hardware accessories for equipment personally owned by a board member, executive director, staff member or researcher.

All sensitive data and programming located on any EBIRE IT equipment will be disposed of in accordance with VA OIT requirements at the VANCHCS.

### **Continuing Education**

Expenditures for continuing education, including scientific books, conference and registration fees, society memberships, etc, specifically relating to a research activity, may be requested by submitting the appropriate documentation to the Executive Director.

Subscriptions or professional association dues, with the exclusion of license fees, may be paid from EBIRE's research or general operating funds upon approval by the Executive Director. All subscriptions must be addressed to a VA address.

## **XII. Sources of Funds, Acceptance & Deposit of Funds**

### **Requirements to Establish Accounts**

EBIRE is a private California nonprofit corporation with exemption from federal taxes under IRS Section 509(a)(1). All checks must be made payable to East Bay Institute for Research and Education. EBIRE's federal tax identification number is #68-0177975.

Correspondence must accompany all checks for deposit. A gift-donation must be accompanied by a letter from the donor indicating that the check represents a gift to be used by the investigator in support of his/her various research programs. Further, the letter should indicate that the gift is irrevocable and does not impose contractual requirements on EBIRE beyond the reporting of research results. EBIRE will provide a written acknowledgement letter to the donor of receipt of the gift.

All checks accepted for deposit represent EBIRE's property and income. The funds are not to be used for personal benefit of any investigator. All interest earned remains EBIRE's property. Expenditures must be for VA research, VA education, or for EBIRE's development.

The Principal Investigator is the individual with direct responsibility for the technical, administrative and fiscal management of a research project. EBIRE will provide quarterly financial reports to research investigators. The investigator should review the project account statements to certify that all costs charged to a contract or grant specifically benefit the project being charged.

All equipment purchased with EBIRE funds remains EBIRE's property at the conclusion of the project. Any equipment removed from VA space must be approved, in writing, in advance by the Executive Director and the Board.

### **Transfers from the General Post Fund**

VA may not transfer funds appropriated to VA to EBIRE except those funds reimbursed to EBIRE under an Intergovernmental Personnel Act (IPA) assignment agreement. VA may transfer to EBIRE non-appropriated funds received by the VA for a specific research or education project with the consent of the donor.

The VANCHCS Research & Development Committee must approve and document all such transfers. EBIRE will document all such transfers of funds to appropriately account for all funds received and the purposes to which the funds will be applied.

### **Transfers of Government Grants from VA to EBIRE**

If VA is currently administering a government grant, two letters must be sent to the granting agency. One letter from VA stating that it is willing to release the grant to EBIRE, and one from EBIRE stating that it is agreeable to administering the grant. Indirect costs will be determined by the EBIRE Board of Directors.

All donations must be made payable to East Bay Institute for Research and Education, not to any individual. Any donation made payable to an individual will be returned to the donor. Any donation not accompanied by a donation letter will be acknowledged in writing by EBIRE. The acknowledgement letter will include the purpose(s) to which EBIRE will apply the donation.

Donations in support of research by a Principal Investigator can only be accepted if the Principal Investigator holds a VA appointment. Such donations can be in support of specific research projects or of a named PI's general research.

Upon receipt, all funds are to be deposited into an appropriate, federally insured, interest-bearing account in the name of EBIRE. Interest income, if any, will be included in the corporate operating fund account.

Principal Investigators will be notified of receipt of funds and when they will be available for use. All research projects must receive a formal review by the VA R&D Committee.

Separate accounting will be kept of unrestricted and restricted funds. All unrestricted gifts, grants or bequests not restricted to a specific Principal Investigator by the donor will be considered available as corporate operating funds unless appropriated by the Board for some specific purpose.

Separate accounting will be maintained for each research project administered by EBIRE. Principal Investigators will be provided with financial statements, at least quarterly, regarding the status/balance of their research account(s).

The administration of funds may depend upon the stipulations of the funding sources.

Funds derived from indirect overhead support provided by sponsored research or education activities administered by EBIRE will be used to support EBIRE's operations and development. These EBIRE funds may also be used to support the needs for direct or indirect research costs or educational and training support identified by the VA R&D Committee, the VA Education Committee, and EBIRE's Board of Directors.

### **XIII. Travel & Business Entertainment**

#### **Acceptable Travel**

Travel to meetings of clinical specialty societies, research societies, national and international general clinical groups recognized or stated primary goals of which are to further medical knowledge, research, public health and/or education is acceptable when the proposed travel has a demonstrable research or education relevance.

#### **Approval Authority**

Approval of proposed corporate travel funding requests is the responsibility of the Executive Director, with final authority for interpretation residing with the Board of Directors. Exceptions to stated policy may be made only by the Board of Directors.

#### **Relevance of Travel**

It is the responsibility of the traveler to submit adequate material to justify a primary research or education purpose.

#### **Advances**

No cash advances or reimbursements of transportation tickets will be made prior to the date of the actual travel. All travel expenses must be paid by the traveler and will be promptly reimbursed upon completion of the approved travel.

The only exception to this policy is that meeting registration fees \$300 and above may be requested in advance. Corporate checks for such registrations will be made out to the organization sponsoring the meeting, not the individual traveler.

#### **Traveler's Responsibility to Obtain Travel Approval**

The Principal Investigator whose funds are to be expended for travel must request authorization to spent those funds in advance from either the Executive Director of EBIRE.

#### **Traveler's Responsibility for Excess Expenses**

The traveler is responsible for excess costs and any additional expenses incurred for personal preference or convenience; e.g. cost of accommodations in excess of conference schedule; luxury accommodations and services unnecessary or unjustified in the performance of official business.

## **Reimbursement Documentation & Time Limits**

Reimbursement will be issued only upon submission of original receipts and documentation.

Reimbursements for completed travel should be requested within 60 days. Requests submitted more than 60 days after the expense is incurred may be denied or may require additional justification and approval before reimbursement can be made.

## **Travel Request Procedure for EBIRE Employees**

The traveler must complete and submit an EBIRE **REQUEST FOR TRAVEL FUNDS** along with the following documents for approval, to the Principal Investigator whose funds will be used:

1. A copy of the meeting/conference announcement or letter of invitation  
If traveler is presenting a paper at the meeting, also attach a copy of the abstract or invitation letter and R&D Committee approval for presentation.
2. The Principal Investigator must indicate which research account funds should be encumbered and then sign the Request for Travel Funds and forward it to EBIRE.
3. EBIRE's Executive Director will determine that there are sufficient funds in the account indicated by the PI and if so, encumber the appropriate amount for final approval.

## **Travel Request Procedure for VA Employees**

The traveler must complete and submit a EBIRE **"REQUEST FOR TRAVEL FUNDS"** along with the following documents for approval, to the Principal Investigator whose funds will be used:

1. A copy of the meeting/conference announcement or letter of invitation. If traveler is presenting a paper at the meeting, also attach a copy of the abstract or invitation letter and R&D Committee approval for presentation.
2. An approved "Request for Approval of Acceptance of Gifts or Donations..." (form 10-010B)  
If Traveler is receiving VA travel orders, a copy of the approved SF-71, requesting "Authorized Leave."
3. The Principal Investigator must complete Part V, Page 2, of the VA form "Request for Approval of Acceptance of Gifts or Donations..." (form 10-010B) and other required documents in support of the request. The PI must sign and submit the "Request for Travel Funds form to EBIRE."
4. The Executive Director will review the request and determine whether sufficient funds are available to encumber.

## **Employee & Board Member Business Travel Reimbursement**

Reimbursement may include payment for the following expenses:

1. Air travel (coach class rates only)
2. Hotel accommodations (single room rate - authorized traveler only)

3. Meals (Actual cost of each meal up to a maximum \$75 per day with original receipts. BBRI will not reimburse for any meal or other travel related expense for which an original receipt is not submitted.)
4. Mileage (current IRS rate)
5. Ground transportation Reimbursement
6. At the conclusion of an EBIRE business trip, an employee or member of the Board that has incurred business-related expenses should complete a "Request for Travel Reimbursement Report" in accordance with the following policies:
  - a. Identify each separately incurred business expense (i.e. do not group all expenses associated with one trip together)
  - b. With the exception of tips and reimbursed mileage, all business expenses must be supported with invoices/receipts.
  - c. For all lodging and any expenditure other than meals, vendor receipts/invoices must be submitted. Credit card charge slips do not represent adequate supporting documentation.
  - d. For airfare, airline-issued receipts should be obtained. If a traveler fails to obtain a receipt, other evidence must be submitted indicating that a trip was taken and the amount paid (for example, a combination of an itinerary, a credit card receipt, and boarding passes).
  - e. Mileage may be reimbursed at the standard federal rates currently in effect, as published each year by the IRS.
  - f. The business purpose of each trip must be adequately explained on each report.
  - g. Project/function codes must be identified for all expenditures.
  - h. For all meals and other business entertainment, the following must be clearly identified:
    1. Names, titles, Corporations, and business relationships of all persons entertained
    2. The business purpose of the entertainment (topics discussed, etc.)
  - i. All expense reports must be signed and dated by the employee.
  - j. All expense reports must be approved by the employee's supervisor.

- k. Only one expense report form should be prepared for each trip.

**NOTE:**

An employee will not be reimbursed for expense reports not meeting the preceding criteria. If the Expense Report results in a balance due to BBRI (as a result of receiving a travel advance greater than actual business expenditures), the employee must attach a check or sign a statement indicating authorization to settle the balance due through a payroll deduction.

No further travel advances will be issued to any employee who has an outstanding balance due to EBIRE from previous business trips.

**Reasonableness of Travel Costs**

EBIRE shall reimburse travelers only for those business-related costs that are reasonably incurred. Accordingly, the following guidelines shall apply:

- a. Suites and other upgraded rooms at hotels shall not be allowed; Travelers should stay in standard rooms
- b. When utilizing rental cars, travelers should rent midsize or smaller vehicles; Share rental cars whenever possible
- c. Business-related long-distance telephone calls while away on business travel are permitted, but should be kept to a minimum; Expense reports should explain long-distance charges
- d. Personal long-distance calls while away on business are reimbursable if kept to a minimum, such as one nightly call home to family; Personal calls in excess of this shall not be reimbursed
- e. Whenever possible, travelers should utilize long-distance calling cards when placing calls while away on travel; Avoid using the hotel's long-distance service if possible
- f. One in-room movie shall be reimbursed; No other entertainment expenses shall be reimbursed
- g. Reasonable tips for baggage handling shall be reimbursed; No receipts are required

**Special Rules Pertaining to Air Travel**

The following additional rules apply to air travel:

- a. Air travel should be at coach class; First class air travel shall not be reimbursed unless there is a documented medical reason
- b. Memberships in airline flight clubs is not reimbursable
- c. Cost of flight insurance is not reimbursable

- d. When returning on a Sunday or departing on a Saturday in order to obtain a cost savings in airfare due to the Saturday-night stay-over, travelers should provide a total cost comparison (showing that the lower airfare plus an extra night lodging is less costly than airfare without the Saturday night stay over)
- e. Cost of upgrade certificates is not reimbursable
- f. Cost of canceling and rebooking flights is not reimbursable, unless it can be shown that it was necessary or required for legitimate business reasons (such as changed meeting dates, etc.)
- g. Cost of canceling and rebooking flights is not reimbursable, unless it can be shown that it was necessary or required for legitimate business reasons (such as changed meeting dates, etc.)
- h. Travelers must identify and pay for all personal flights, even if such flights are incorporated into a flight schedule that serves that business purpose(i.e. EBIRE will not reimburse for the personal leg of a trip)
- i. Persons traveling on EBIRE funds **cannot** use government rate airfares.

### **Spouse/Partner Travel**

It is the policy of EBIRE not to reimburse any employee or board member for separate travel costs (air fare, etc.) associated with his/her spouse or partner. The cost of a shared hotel room need not be allocated between employee/director and spouse/partner for purposes of this policy.

### **Cost Reimbursements to VA**

EBIRE will enter into a MOU with the VAMC for the purpose of making cost reimbursements to VA is to ensure that the VANCHCS is properly reimbursed at an appropriate rate for costs incurred in the performance of a research study that are considered above and beyond standard of care. Prior to the initiation of a study, a proper budget must be negotiated with the sponsor. Researchers must involve the Executive Director when assessing and developing budgets for clinical care projects that are administered through EBIRE.

### **Accounts Receivable Management**

1. **Monitoring and Reconciliations:** On a monthly basis, a detailed accounts receivable report (showing aged, outstanding invoices by client) is generated and reconciled to the general ledger. All differences are immediately investigated and resolved, and the reconciliation is reviewed and approved by the EBIRE Executive Director.
2. **Collections:** Collections are performed on a monthly basis, according to a review of the outstanding items shown on the accounts receivable aging report. This report shows the current month's activity for each customer and prior month's balances outstanding for 30, 60, 90 and 120 days past due.

- a. Clients with unpaid balances receive statements every 30 days. After a balance is unpaid for 60 days, the Executive Director will contact the client by telephone attempting to collect the amount due.
3. **Credits & Other Adjustments to Accounts Receivable:** From time to time, credits against accounts receivable from transactions other than payments and bad debts will occur. For example, credits may be made to correct for billing errors. An employee who is independent of the cash receipts function shall process all credits. In addition, the EBIRE Executive Director will authorize all credits.
4. **Accounts Receivable Write-Off Authorization Procedures:** All reasonable means of collecting accounts receivable will have been exhausted before write-offs are taken.
  - a. If an account receivable is deemed uncollectible, both the Executive Director and the Secretary/Treasurer will approve the write-off.
  - b. Once a write-off has been processed, actions will be taken to ensure that further credit is not granted and to update the master list of bad debt accounts.
  - c. Clients listed as poor credit risks will be extended future credit only if the back debt is paid and the client is no longer deemed high-risk for collection.
  - d. If write-off procedures have been initiated, the following accounting treatment applies:
    - i. Current year invoices that are written off will either be charged against an appropriate revenue or revenue adjustment account or against the original account credited.
    - ii. Invoices written off that are dated prior to the current year will be treated as bad debts and will reduce the allowance for doubtful accounts.

## **XIV. Federal Grant Applications**

### **1) NIH Applications**

Federal grant applications are submitted on-line. This process can be capitated in to six (6) steps:

1. Completion of SF424
2. Format of Attachments
3. Scientific Attachments
4. All Other attachments
5. Budget Documents
6. Error corrections & Final Confirmation

#### **1. Completion of the SF424, not including the attachments**



- i) This section describes the steps an applicant takes once the appropriate FOA has been located and the corresponding grant application package has been successfully downloaded.
- ii) Verify Grant Information:
  - (1) When you select a funding opportunity in Grants.gov, verify that the information shown in the Grant Application Package screen corresponds to the funding opportunity for which you wish to apply.
  - (2) Grants.gov will auto-populate the following information: Opportunity title, Offering agency, CFDA number, CFDA description, Opportunity number, Competition ID, Opportunity open date, Opportunity close date, and Agency contact.
- iii) Enter the Name for the Application: Enter a name for the application in the Application Filing Name field (required).
  - (1) This name is for use solely by the applicant for tracking the application through the Grants.gov submission process and will not be used by the receiving agency.
- iv) Click the check box next to the form name to add the form to the application package.
  - (1) To navigate to the form, click on the form name.
  - (2) To remove an optional form from the application package, uncheck the box next to the form name.
- v) Open and Complete Mandatory Documents:
  - (1) Click the form name to navigate to the form in the application package and complete all of the Mandatory forms.
  - (2) Complete the form titled SF424 (R&R) first.
  - (3) Data entered in this form populates other mandatory and optional forms where applicable.
- vi) Open and Complete Optional Documents:
  - (1) These documents can be used to provide additional information for the application or may be required for specific types of grant activities.
  - (2) In some application packages, applicants will see two budget options; e.g. Research & Related Budget and PHS 398 Modular Budget in the Optional Documents section.
  - (3) While both appear as optional documents, one or the other will always be required.

## 2. Format of Attachments

- i) NIH and other PHS agencies require all text attachments to the Adobe application forms be submitted as PDFs and that all text attachments conform to the agency-specific formatting requirements noted below. Failure to follow these requirements may lead to rejection of the application during agency validation or delay in the review process.
- ii) Text attachments should be generated using word processing software and then converted to PDF using PDF generating software. Avoid scanning text attachments to convert to PDF since that causes problems for the agency handling the application. Additional tips for

creating PDF files can be found at

[http://grants.nih.gov/grants/ElectronicReceipt/pdf\\_guidelines.htm](http://grants.nih.gov/grants/ElectronicReceipt/pdf_guidelines.htm).

iii) File Name

- (1) Save all files with descriptive file names of 50 characters or less. Do not use the ampersand (&) character in file names.

iv) Font

- (1) Prepare the application using Arial typeface in black font color. After text attachments are converted to PDF, font size in each final PDF document must be 11 point.
- (2) Since some PDF converters may reduce font sizes, it is important to confirm that type density in each final PDF document, including both characters and spaces, is no more than 15 characters+spaces per linear inch and no more than six lines per vertical inch.

v) Paper Size and Page Margins

- (1) Final PDF documents should be formatted to be no larger than standard paper size (8 ½" x 11).
- (2) The final PDF document should have at least one-half inch margins (top, bottom, left, and right) for all pages. No information should appear in the margins, including the PI's name and page numbers.

vi) Page Formatting

- (1) Since a number of reviewers will be reviewing applications as an electronic document and not a paper version, applicants are strongly encouraged to use only a standard, single-column format for the text. Avoid using a two-column format since it can cause difficulties when reviewing the document electronically.
- (2) Do not include any information in a header or footer of the attachments. A header will be system-generated that references the name of the PD/PI. Page numbers for the footer will be system-generated in the complete application, with all pages sequentially numbered.

vii) Figures, Graphs, Diagrams, Charts, Tables, Figure Legends, and Footnotes

- (1) You may use a smaller type size but it must be in a black font color, readily legible, and follow the font typeface requirement. Color can be used in figures; however, all text must be in a black font color, clear and legible.

viii) Page Limits

- (1) Although many of the sections of this application are separate text (PDF) attachments, page limits referenced in these instructions and/or funding opportunity announcement must still be followed. Applications found not to comply with the requirements may lead to rejection of the application during agency validation.
- (2) All applications for NIH and other PHS agency funding must be self-contained within specified page limits. Unless otherwise specified in an NIH solicitation, Internet website addresses (URLs) may not be used to provide information necessary to the review because reviewers are cautioned that they should not directly access an Internet site.

- (3) Observe the page number limits given in the detailed Table of Page Limits at [http://grants.nih.gov/grants/forms\\_page\\_limits.htm](http://grants.nih.gov/grants/forms_page_limits.htm). Only when specifically allowed in an FOA will the PHS accept applications that exceed the page number limitations noted in the Table. The page number limitations may also be different for other specialized grant applications.
- (4) Applicants are prohibited from using the Appendix to circumvent page limitations in any section of the application for which a page limit applies.

### **3. Scientific Attachments**

- i) This section of the application is to be completed by PI. This is typically a collection of scientific publications, data, etc. that is sent to EBIRE. EBIRE will change the format of these scientific attachments to one that works for the SF424 application.

### **4. Budget Documents**

- i) The application forms package associated with most NIH research grant funding opportunities includes two optional budget forms: (1) SF424 (R&R) Budget and (2) PHS 398 Modular Budget.
- ii) NIH application submissions must include either the SF424 (R&R) Budget Form or the PHS 398 Modular Budget Form, but never both. Unless otherwise stated in a funding announcement, an application must always be submitted with a budget form.
- iii) For a small number of programs (e.g., S10, DP1, DP2, DP3, X01, X02), neither budget form is included and the only budget information required is the Estimated Project Funding section of the SF424 (R&R) cover.
- iv) SF424 (R&R) Budget Form: The R&R Budget form includes three separate data entry screens: (1) Sections A and B; (2) Sections C through E; and (3) Sections F through K. To navigate between the various screens, use the Previous and Next buttons at the top of the form or use the scroll bar on the side of the screen.
  - (1) Complete the R&R Budget form following the instructions provided.
  - (2) You must complete a separate detailed budget for each year of support requested.
  - (3) The form will generate a cumulative budget for the total project period.
  - (4) You must complete all the required information (i.e., those fields that are highlighted and outlined in red) before the Next Period button is activated. If no funds are requested for a required field, enter "0."
  - (5) While the dollar fields allow cents to be entered, all dollar fields should be presented in whole numbers. Please round to the nearest whole number.
  - (6) NIH and other PHS agencies use the concept of person months as a metric for determining percent of effort. To assist applicants unfamiliar with this concept, resources are available on the web at:

[http://grants.nih.gov/grants/policy/person\\_months\\_faqs.htm](http://grants.nih.gov/grants/policy/person_months_faqs.htm). Frequently asked questions and a conversion calculator are available.

- (7) If funds are being requested for more than one budget period, click the Next Period button at the top of the third budget screen (Sections F through K) to navigate to screens for the next budget period.
  - (8) Revision (Supplemental) Application. For a “Revision” (Supplemental) application, show only those items for which additional funds are requested. If the initial budget period of the supplementation application is less than 12 months, prorate the personnel costs and other appropriate items of the detailed budget.
  - (9) For more detailed instructions on how to complete the budget forms, refer to Sections 4.7 (R&R) and 5.4 (Modular) of the NIH SF424 R&R Application Guide for Adobe Forms Version C, found at [http://grants.nih.gov/grants/funding/424/SF424\\_RR\\_Guide\\_General\\_VerC.pdf](http://grants.nih.gov/grants/funding/424/SF424_RR_Guide_General_VerC.pdf).
- v) PHS 398 Modular Budget Form: Modular budgets are applicable to certain research grant applications from domestic organizations requesting \$250,000 or less per year for direct costs.
- (1) Note, consortium/contractual F&A costs are not factored into the direct cost limit. Consortium F&A costs may be requested in addition to the \$250,000 limit.
  - (2) The modular budget is applicable only to applications for R01, R03, R15, R21, and R34 and their corresponding cooperative agreement activity codes.
  - (3) For all modular budgets, request total direct costs (in modules of \$25,000), reflecting appropriate support for the project. There will be no future year escalations.

**5. All other attachments, including but not limited to: biosketches, study narrative, etc.**

- i) Pre-Application
  - (1) Unless specifically noted in a Funding Opportunity Announcement, NIH and other PHS agencies do not use Pre-applications and this attachment field should not be used for any other purpose.
  - (2) If submitting a pre-application, provide a summary description of the project in accordance with the announcement and/or agency specific instructions.
- ii) Cover Letter
  - (1) Attach the cover letter in accordance with the announcement and/or the agency specific instructions.
  - (2) The cover letter should not be used for post-award submissions such as administrative supplements, change of grantee institution, or successor-in-interest. The letter should contain any of the following information that applies to the application:
    - (a) Application title.
    - (b) Funding Opportunity (PA or RFA) title of the NIH initiative.
    - (c) Request of an assignment (referral) to a particular awarding component(s) or Scientific Review Group (SRG). The PHS makes the final determination.
    - (d) List of individuals (e.g., competitors) who should not review your application and why.

- (e) Disciplines involved, if multidisciplinary.
- (f) Explanation of any subaward budget components that are not active for all periods of the proposed grant.
- (g) Statement that you have attached any required agency approval documentation for the type of application submitted. This may include approval for applications \$500,000 or more, approval for Conference Grant or Cooperative Agreement (R13 or U13), etc.

(3) Suggested Cover Letter Format

- (a) The Division of Receipt and Referral (DRR), Center for Scientific Review (CSR) is responsible for assigning applications to ICs and to Scientific Review Groups (SRGs). DRR will be utilizing knowledge management approaches as an adjunct to the work of referral experts as part of an overall plan to shorten the time from submission to review. Analysis has shown that requests made by investigators are a valuable source of information in this process. In order to facilitate the use of these requests in conjunction with knowledge management analysis of the content of the application, applicants are requested to use the following format when assignment requests are contained in a cover letter.
  - (i) List one request per line.
  - (ii) Place Institute/Center (IC) and SRG review requests (if both are made) on separate lines.
  - (iii) Place positive and negative requests (if both are made) on separate lines.
  - (iv) Include name of IC or SRG, followed by a dash and the acronym. Do not use parentheses.
  - (v) Provide explanations for each request in a separate paragraph.

iii) Specific Aims

- (1) State concisely the goals of the proposed research and summarize the expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.
- (2) List succinctly the specific objectives of the research proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.
- (3) The Specific Aims attachment is required unless otherwise specified in the FOA.

iv) Research Strategy

- (1) Organize the Research Strategy in the specified order and using the instructions provided below, or as stated in the Funding Opportunity Announcement. Start each section with the appropriate section heading – Significance, Innovation, Approach. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section.
- (2) Significance
  - (a) Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
  - (b) Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.

- (c) Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.
- (3) Innovation
  - (a) Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
  - (b) Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
  - (c) Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.
- (4) Approach
  - (a) Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in the Resource Sharing Plan attachment below, include how the data will be collected, analyzed, and interpreted.
  - (b) Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.
  - (c) If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.
  - (d) Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of select agents should appear in the Select Agent Research attachment, below.
- (5) Preliminary Studies for New Applications: For new applications, include information on Preliminary Studies. Discuss the PD/PI's preliminary studies, data, and or experience pertinent to this application. Except for Exploratory/Developmental Grants (R21/R33), Small Research Grants (R03), and Academic Research Enhancement Award (AREA) Grants (R15), preliminary data can be an essential part of a research grant application and help to establish the likelihood of success of the proposed project. Early Stage Investigators should include preliminary data.
- (6) Progress Report for Renewal and Revision Applications. For renewal/revision applications, provide a Progress Report. Provide the beginning and ending dates for the period covered since the last competitive review. Summarize the specific aims of the previous project period and the importance of the findings, and emphasize the progress made toward their achievement. Explain any significant changes to the specific aims and any new directions including changes to the specific aims and any new directions including changes resulting from significant budget reductions. A list of publications, patents, and other printed materials should be included in the Progress Report Publication List attachment.
- v) Progress Report Publication List
  - (1) List the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g.,

NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these journals is posted at: [http://publicaccess.nih.gov/submit\\_process\\_journals.htm](http://publicaccess.nih.gov/submit_process_journals.htm).

- (2) Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference (note that copies of these publications are not accepted as appendix material).

vi) Protection of Human Subjects

- (1) Complete this section if you answered "yes" to the question "are human subjects involved?" on the R&R Other Project Information Form. If you answered "no" to the question but your proposed research involves human specimens and/or data from subjects you must provide a justification in this section for your claim that no human subjects are involved.
- (2) Refer to Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan for detailed instructions. It can be found at [http://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf#4\\_1\\_Protection\\_of\\_Human\\_Subject](http://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf#4_1_Protection_of_Human_Subject).

vii) Inclusion of Women and Minorities

- (1) Complete this section if you answered "yes" to the question "are human subjects involved?" on the R&R Other Project Information Form and the research does not fall under Exemption 4.
- (2) Refer to Part II, Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan for detailed instructions. It can be found at [http://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf#4\\_1\\_Protection\\_of\\_Human\\_Subject](http://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf#4_1_Protection_of_Human_Subject).

viii) Inclusion of Children

- (1) Complete this section if you answered "yes" to the question "are human subjects involved?" on the R&R Other Project Information Form and the research does not fall under Exemption 4.
- (2) Refer to Supplemental Instructions for Preparing the Human Subjects Section of the Research Plan, Sections 4.4 and 5.7. It can be found at [http://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf#4\\_1\\_Protection\\_of\\_Human\\_Subject](http://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf#4_1_Protection_of_Human_Subject).

ix) Vertebrate Animals

- (1) If Vertebrate Animals are involved in the project, address each of the five points below.
  - (a) Provide a detailed description of the proposed use of the animals in the work outlined in the Research Strategy section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.
  - (b) Justify the use of animals, the choice of species, and the numbers to be used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and numbers.
  - (c) Provide information on the veterinary care of the animals involved.
  - (d) Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or

comfortable restraining devices, where appropriate, to minimize discomfort, distress, pain, and injury.

- (e) Describe any method of euthanasia to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines on Euthanasia. If not, include a scientific justification for not following the recommendations.
  - (2) If all or part of the proposed research involving vertebrate animals will take place at alternate sites (such as project/performance or collaborating site(s)), identify those sites and describe the activities at those locations. If the involvement of animals is indefinite, provide an explanation and indicate when it is anticipated that animals will be used. Although no specific page limitation applies to this section of the application, be succinct.
  - (3) For additional information, see <http://grants.nih.gov/grants/olaw/VASchecklist.pdf>.
- x) Select Agent Research
- (1) Select agents are hazardous biological agents and toxins that have been identified by DHHS or USDA as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. CDC and the Animal APHIS Select Agent Programs jointly maintain a list of these agents. See <http://www.selectagents.gov/>.
  - (2) If any of the activities proposed in your application involve the use of select agents at any time during the proposed project period, either at the applicant organization or at any other performance site, address the following three points for each site at which select agent research will take place. Although no specific page limitation applies to this section, be succinct.
    - (a) Identify the select agent(s) to be used in the proposed research.
    - (b) Provide the registration status of all entities\* where select agent(s) will be used.
      - (i) If the performance site(s) is a foreign institution, provide the name(s) of the country or countries where select agent research will be performed.
    - (c) Provide a description of all facilities where the select agent(s) will be used.
      - (i) Describe the procedures that will be used to monitor possession, use and transfer of the select agent(s).
      - (ii) Describe plans for appropriate biosafety, biocontainment, and security of the select agent(s).
      - (iii) Describe the biocontainment resources available at all performance sites.
- xi) Multiple PD/PI Leadership Plan
- (1) For applications designating multiple PD/PIs, a leadership plan must be included. For applications designating multiple PD/PIs, all such individuals must be assigned the PD/PI role on the Senior/Key Profile form, even those at organizations other than the applicant organization. A rationale for choosing a multiple PD/PI approach should be described. The governance and organizational structure of the leadership team and the research project should be described, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts. The roles and administrative, technical, and scientific responsibilities for the project or program should be delineated for the PD/PIs and other collaborators. Do not submit a leadership plan if you are not submitting a Multiple PD/PI application.



- (2) If budget allocation is planned, the distribution of resources to specific parts of the project or the individual PD/PIs should be delineated in the Leadership Plan.

xii) Consortium/ Contractual Arrangements

- (1) Explain the programmatic, fiscal, and administrative arrangements to be made between the applicant organization and the consortium organization(s). If consortium/contractual activities represent a significant portion of the overall project, explain why the applicant organization, rather than the ultimate performer of the activities, should be the grantee. The signature of the Authorized Organization Representative on the SF424 (R&R) form signifies that the applicant and all proposed consortium participants understand and agree to the following statement:
  - (a) The appropriate programmatic and administrative personnel of each organization involved in this grant application are aware of the agency's consortium agreement policy and are prepared to establish the necessary inter-organizational agreement(s) consistent with that policy.

xiii) Letters of Support

- (1) Attach all appropriate letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the grant application.
  - (a) Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project.
  - (b) Letters should stipulate expectations for co-authorship, and whether cell lines, samples or other resources promised in the letter are freely available to other investigators in the scientific community or will be provided to the particular investigators only.
  - (c) For consultants, letters should include rate/charge for consulting services and level of effort/number of hours per year anticipated. Consultant biographical sketches should be in the Biographical Sketch section.
  - (d) Do not place these letters in the Appendix.

xiv) Resource Sharing Plan(s)

- (1) Data Sharing Plan: Investigators seeking \$500,000 or more in direct costs (exclusive of consortium F&A) in any year are expected to include a brief 1-paragraph description of how final research data will be shared, or explain why data-sharing is not possible. Specific Funding Opportunity Announcements may require that all applications include this information regardless of the dollar level. Applicants are encouraged to read the specific opportunity carefully and discuss their data-sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application. See Data-Sharing Policy or <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html>.
- (2) Sharing Model Organisms: Regardless of the amount requested, all applications where the development of model organisms is anticipated are expected to include a description of a specific plan for sharing and distributing unique model organisms or state why such sharing is restricted or not possible. See Sharing Model Organisms Policy, and NIH Guide NOT-OD-04-042.
- (3) Genome Wide Association Studies (GWAS): Applicants seeking funding for a genome-wide association study are expected to provide a plan for submission of GWAS data to

the NIH-designated GWAS data repository, or an appropriate explanation why submission to the repository is not possible. GWAS is defined as any study of genetic variation across the entire genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight) or the presence or absence of a disease or condition. For further information see Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, NIH Guide NOT-OD-07-088, and <http://gwas.nih.gov/>.

xv) Appendix (if applicable)

- (1) Only one copy of appendix material is necessary. Use the Add Attachments button to the right of this field to complete this entry.
- (2) A maximum of 10 PDF attachments is allowed in the Appendix. If more than 10 appendix attachments are needed, combine the remaining information into attachment #10.
- (3) Do not use the appendix to circumvent the page limits of the Research Strategy or any other section of the application for which a page limit applies. For additional information regarding Appendix material and page limits, please refer to the NIH Guide Notice NOT-OD-11-080, <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-080.html>.
- (4) Appendix material may not appear in the assembled application in the order attached, so it is important to use filenames for attachments that are descriptive of the content. A summary sheet listing all of the items included in the appendix is also encouraged but not required. When including a summary sheet, it should be included in the first appendix attachment.
- (5) New, resubmission, renewal, and revision applications may include the following materials in the Appendix (note, however, that some FOAs do not permit publications):
  - (a) Publications – No longer allowed as appendix materials except in the circumstances noted below. Applicants may submit up to 3 of the following types of publications:
    - (i) Manuscripts and/or abstracts accepted for publication but not yet published: The entire article should be submitted as a PDF attachment.
    - (ii) Manuscripts and/or abstracts published, but a free, online, publicly available journal link is not available: The entire article should be submitted as a PDF attachment.
    - (iii) Patents directly relevant to the project: The entire document should be submitted as a PDF attachment.
- (6) Items that must not be included in the appendix:
  - (a) Digital images of gels, micrographs, etc., are not accepted as Appendix material. These images must be included in the Research Strategy PDF. However, images embedded in publications are allowed.
  - (b) Publications that are publicly accessible. For such publications, the URL or PMC submission identification numbers along with the full reference should be included as appropriate in the Bibliography and References cited section, the Progress Report Publication List section, and/or the Biographical Sketch section.

xvi) Biosketch for PD/PI and Senior/Key Person(s)

- (1) This section must contain the biographical sketches of all individuals listed as Senior/key Personnel and Other Significant Contributors. All individuals who have the

PD/PI role must be registered in the eRA Commons, and must include the assigned Commons User Name.

- (2) Use the sample format on the Biographical Sketch Format Page to prepare this section for all grant applications. The Biographical Sketch may not exceed 4 pages. This 4-page limit includes the table at the top of the first page. (See sample of a completed Biographical Sketch:

[http://grants.nih.gov/grants/funding/phs398/phs398.html#biosample.](http://grants.nih.gov/grants/funding/phs398/phs398.html#biosample))

xvii) Project Summary/Abstract

- (1) State the application's broad, long-term objectives and specific aims, making reference to the health relatedness of the project (i.e., relevance to the mission of the agency). Describe concisely the research design and methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person.
- (2) This section must be no longer than 30 lines of text, and follow the required font and margin specifications. An abstract which exceeds this allowable length may be flagged as an error by the agency upon submission. This would require a corrective action before the application will be accepted.
- (3) Do not include proprietary, confidential information or trade secrets in the description section.

xviii) Project Narrative

- (1) For NIH and other PHS agencies applications, using no more than two or three sentences, describe the relevance of this research to public health. In this section, be succinct and use plain language that can be understood by a general, lay audience.

xix) Bibliography and References Cited

- (1) Unless otherwise noted in an FOA, this section is required for submissions to NIH and other PHS agencies. This section should include any references cited in the PHS 398 Research Plan form. When citing articles that fall under the Public Access Policy, were authored or co-authored by the applicant and arose from NIH support, provide the NIH Manuscript Submission reference number (e.g., NIHMS97531) or the PubMed Central (PMC) reference number (e.g., PMCID234567) for each article. If the PMCID is not yet available because the Journal submits articles directly to PMC on behalf of their authors, indicate "PMC Journal - In Process." A list of these journals is posted at: [http://publicaccess.nih.gov/submit\\_process\\_journals.htm](http://publicaccess.nih.gov/submit_process_journals.htm).
- (2) Citations that are not covered by the Public Access Policy, but are publicly available in a free, online format may include URLs or PubMed ID (PMID) numbers along with the full reference. The references should be limited to relevant and current literature.

xx) Facilities and Other Resources

- (1) This information is used to assess the capability of the organizational resources available to perform the effort proposed. Identify the facilities to be used (Laboratory, Animal, Computer, Office, Clinical and Other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work. Provide any information describing the Other Resources available to the project (e.g., machine shop, electronic shop) and the extent to which they would be available to the project.

- (2) Describe any special facilities used for working with biohazards or other potentially dangerous substances.
- (3) If there are multiple performance sites, describe the resources available at each site.
- xxi) Equipment
  - (1) List major items of equipment already available for this project and, if appropriate identify location and pertinent capabilities.
- xxii) Other Attachments
  - (1) Attach a file only to provide any other project information not provided above or in accordance with the announcement and/or agency-specific instruction.
- xxiii) Budget Justifications
  - (1) Personnel Justification
    - (a) List all personnel, including names, percent of effort and roles on the project. To assist applicants, resources are available on the web at [http://grants.nih.gov/grants/policy/person\\_months\\_faqs.htm](http://grants.nih.gov/grants/policy/person_months_faqs.htm).
    - (b) No individual salary information should be provided.
  - (2) Consortium Justification
    - (a) Provide an estimate of total costs (direct plus Facilities and Administrative) for each year, rounded to the nearest \$1,000. List the individuals/ organizations with whom consortium or contractual arrangements have been made. List all personnel, including percent of effort, using the metric of person months, and roles on the project. No individual salary information should be provided. Indicate whether the collaborating institution is foreign or domestic. While only the direct cost for a consortium/contractual arrangement is factored into eligibility for using the modular budget format, the total consortium/contractual costs must be included in the overall requested modular direct cost amount.

## 6. Electronic Submission

- i) Application Forms: The majority of competing applications now require an electronic application submission. The Funding Opportunity Announcement (FOA) to which you are applying will identify whether you must submit electronically or use paper submission. Electronic submissions require the SF424 (R&R) application and paper submissions require the PHS 398 application form.
- ii) Submission Dates: The FOA will provide discrete application deadlines or will refer to the NIH's standard due dates found at <http://grants.nih.gov/grants/funding/submissionschedule.htm>
  - (1) Expedited Standing Submission Dates: April 1, April 5, April 15, May 1, August 1, August 5, August 15, September 1, December 1, December 5, December 15, and January 2. Applications must be received at the NIH within one week of the standing submission date.
- iii) Electronic Application Submission: Electronic submission involves two separate systems working together – Grants.gov and eRA Commons. This will require institutions to register with Grants.gov and NIH eRA Commons. Principal Investigators (PIs) also will need to

make sure they are registered with the eRA Commons. The Applying Electronically website (<http://grants.nih.gov/grants/ElectronicReceipt/index.htm>) and the application guide (<http://grants.nih.gov/grants/funding/424/index.htm>) provide in-depth instructions for submitting an application electronically.

(1) Submitting the Application via Grants.gov:

- (a) Once you have properly completed all required documents and attached any required or optional documentation, click on the Check Package for Errors button to ensure that you have successfully completed all required data fields.
- (b) If any of the fields required by Grants.gov are not completed you will receive an error notice which will indicate where revision is needed.
- (c) Correct any errors or if none are found, save the application package.
- (d) The Save & Submit button will now become active and clicking this button will begin the application submission process.
- (e) Only after the package has been saved with no errors will the Save & Submit button become active.
- (f) The application package must then be saved once more before the submission process begins.
- (g) Only an AOR will be able to perform the submit action and they will be taken to the applicant login page to enter the Grants.gov username and password that was established in the Grants.gov registration process.

## 7. Error corrections and final confirmation

- i) Submit the application online at least 72 hours before the application deadline. This allows EBIRE to review the application for any errors and make the appropriate changes.
- ii) Once the application has been reviewed and submitted, confirm that the application has been received by grants.gov/NIH.

## 8. For Assistance

- i) If help to prepare the application after reviewing the application instruction guide, contact GrantsInfo: (301) 435-0714, [GrantsInfo@nih.gov](mailto:GrantsInfo@nih.gov)
- ii) If help is needed with the Grants.gov registration process or with the technical aspects of submitting an application through the Grants.gov system, first check the resources available at Grants.gov. **If you are on deadline for submitting an application and are experiencing technical difficulties with the submission, contact the Grants.gov and eRA Commons Help Desk immediately.** Grants.gov customer support:
  - i. Grants.gov Program Management Office
  - ii. 200 Independence Avenue, SW
  - iii. HHH Building, Room 739F
  - iv. Washington, DC 20201

- iii) If help is needed with the eRA Commons registration process for the applicant organization and PD/PIs; with using ASSIST for the preparation and submission of multi-project applications; or with the application validation process in the Commons after submission through Grants.gov, check first the resources available at the Application Electronically website: <http://grants.nih.gov/grants/ElectronicReceipt/index.htm>. eRA Commons customer support:
- i. eRA Website: <http://era.nih.gov/>
  - ii. eRA Commons Website:  
<https://commons.era.nih.gov/commons/index.jsp>
  - iii. eRA Commons On-line Resources and Web Ticketing:  
<http://grants.nih.gov/support/>
  - iv. eRA Commons Help Desk Email: [commons@od.nih.gov](mailto:commons@od.nih.gov)
  - v. eRA Commons Phone: (301) 402-7469, (866) 504-9552 (Toll Free)
  - vi. The eRA Commons Help Desk hours of operation are Monday-Friday from 7:00 a.m. to 8:00 p.m. EST (except Federal holidays).

## **XV. Forms**

**HANDBOOK ENDS HERE**