

Policies Governing the Award of Research Grants

Table of Contents

Section I.	Compliance	1
Section II.	Description of Grants Program	1
Section III.	Authority for Making Grants.....	1
Section IV.	Term of Support and Disbursements.....	1
Section V.	Sources of Funds	2
Section VI.	Eligibility	2
Section VII.	Confidentiality of Information	2
Section VIII.	Application Procedure	3
Section IX.	Project Schedule	6
Section X.	Uses of Funds	6
Section XI.	Ownership of Equipment	8
Section XII.	Other Support.....	8
Section XIII.	Continuing Support.....	8
Section XIV.	Research Involving Human Subjects or Animals.....	9
Section XV.	Transfer of a Grant	9
Section XVI.	Termination of a Grant	9
Section XVII.	Intellectual Property and Data Sharing.....	10
Section XVIII.	Reporting Requirements	11
Section XIX.	Approval and Revision of Policies	12

Approved May 29, 2008

The CFIDS Association of America

Policies Governing the Award of Research Grants

I. Compliance

The CFIDS Association of America (“Association”) requires that all investigators, collaborators and sub-contractors who receive funding through the Association’s Grants Program comply with these Policies Governing the Award of Research Grants (“Policies”). Investigators will be provided a copy of current Policies when invited to apply for funding. Submission of an application requires signed agreement to comply with these policies by the Principal Investigator and an authorized representative of the applicant’s institution. At the time of preliminary award (described in Section VIII., below), funded investigators will be provided a copy of the current Policies. As a condition of the award, the Principal Investigator, all external collaborators, subcontractors, consultants and representatives from each institution will be required to submit signed copies of an agreement to comply with the Policies (described in Section VIII., below).

II. Description of Grants Program

Established in 1987, the CFIDS Association of America is the world’s leading organization working to conquer chronic fatigue syndrome (CFS). The Association works toward this mission by building recognition of CFS as a serious, widespread medical disorder; securing a meaningful response to CFS from the federal government; stimulating high quality CFS research; improving health care providers’ abilities to detect, diagnose and manage CFS; providing information to persons with CFS; and enabling the CFS community to speak with a collective voice.

Between 1987 and 2007, the Association provided a total of \$4.8 million in direct support of CFS research studies, hosted scientific symposia and co-sponsored meetings to identify promising areas of investigation. To meet the unequivocal need for a more robust scientific enterprise for CFS, in November 2007 the CFIDS Association’s Board of Directors announced the Campaign to Accelerate CFS Research to fuel a more intensive search for biomarkers, better diagnostics and more effective treatments. The current purpose of the CFIDS Association’s research program is to accelerate progress toward accurate diagnosis and effective treatment of CFS by directly supporting research studies, facilitating collaboration among investigators and pursuing increased investment in CFS research by public, private and commercial institutions. The Association will periodically issue Requests for Applications in areas consistent with these objectives. The timing of and priorities for all funding opportunity announcements will depend on evolving scientific opportunities and budgetary factors.

III. Authority for Making Grants

As a private, non-profit foundation authorized under Internal Revenue Service code 501(c)(3), the CFIDS Association of America, Inc. awards grants in furtherance of its mission, including providing support for scientific research on CFS. Grant decisions rest with the Executive Committee of the Board of Directors of the Association, acting upon the recommendations of a Scientific Advisory Committee, which conducts a peer review of the scientific merit of applications submitted to the Association’s Research Grants Program, and such other advisory committees as the Board of Directors may appoint.

IV. Term of Support and Disbursements

Grants are approved for a maximum term of 18 months. Equal quarterly disbursements are made over the term of the grant contingent upon full compliance with the Association’s Grants Policies in effect during the term of the grant, including reporting requirements as detailed in Section XVIII., below.

V. Sources of Funds

The number and size of grant awards made by the Association's Board of Directors is contingent upon the availability of the necessary funds. Private donations comprise the principal source of research funds raised by the Association.

Periodically the Association receives donations earmarked for particular research projects. In these instances a grant will only be awarded if the application meets peer review criteria and is approved for funding by the Executive Committee of the Association's Board of Directors. Receipt by the Association of an earmarked gift does not guarantee or imply that a grant will be awarded. In instances where an award is not made, the Association will contact the donor of earmarked funds to make other provisions for the use or return of the gift.

VI. Eligibility

- A. Institutions: Institutions eligible for Association support include nonprofit, public and commercial institutions with no restrictions as to geographic location.
- B. Agencies: Federal and state government agencies and their employees are not eligible for Association grants.
- C. Postdoctoral Fellows: Postdoctoral fellows are eligible for Association support. Any postdoctoral fellow requesting support is required to collaborate with an Administrative Principal Investigator who serves as the director of the laboratory or facility in which the research will be conducted. The Administrative Principal Investigator will be responsible for assisting in providing all institutional documents required for the project and will be required to sign any award. Responsibility for the planning, direction and execution of the proposed project will be solely that of the postdoctoral fellow, acting as Principal Investigator. For proposals involving postdoctoral fellows as applicants, biographical information is required for both the postdoctoral fellow and the Administrative Principal Investigator.
- D. Association Personnel: Current members of the Association's Board of Directors, professional staff and Scientific Advisory Committee are not eligible to apply for or receive Association research grants. However, they may serve as unpaid consultants, collaborators, or co-investigators once an award has been made. Board, staff or Scientific Advisory Committee members may apply for research funding as principal investigators once their service with the Association has ended.
- E. Other Eligibility Requirements:
 - 1. Applicants for funding are required to submit written documentation of financial stability (as specified on the grant application form), compliance with applicable accreditation, and approvals for conducting biomedical research. All financial information will be kept strictly confidential in accordance with the provisions of Section VII., below.
 - 2. Any institution that receives grant funds from the Association must have written policy guidelines on conflict of interest and fraud. It is the responsibility of the grantee institution and the investigator to inform the Association immediately and in writing of any investigation into the conduct of an investigator supported with Association funds, regardless of whether the conduct at issue was related to Association supported research, and to inform the Association in a timely manner of the progress and outcome of such investigation. A finding that the investigator is guilty of scientific fraud or misconduct is grounds for immediate termination of Association funding.
 - 3. Grantee institutions located in the U.S. must comply with federally mandated equal opportunity policies and all other applicable state and federal law.
 - 4. Principal Investigators who have been supported by Association grants in the past must have fulfilled all reporting and other compliance requirements in force at the time of their earlier award(s) to be eligible to apply for new grant funding from the Association.

VII. Confidentiality of Information

- A. Confidential Information: The Association treats all Letters of Intent, applications, financial information, research projects, quarterly reports, and associated research information (collectively, the "Confidential Information") in confidence using no less than reasonable care in protecting such Confidential Information from disclosure to third parties who do not participate in the grant review process.

- B. Confidentiality Agreements: The Association will use its best efforts and reasonable care to protect confidential or proprietary information submitted pursuant to the grant application process. Members of the Association's Board of Directors, its staff and the external Scientific Advisory Committee are required to sign Confidentiality Agreements. A copy of the Association's standard Confidentiality Agreement form is available upon request.
- C. Use of Confidential Information: All Confidential Information will be used by the Association and its grant reviewers only internally for the purposes of reviews and assessments, and will be shared only in accordance with these Policies.
- D. Reasonable Care: The Association will maintain the confidentiality of the Confidential Information using no less than the same degree of care and protections as are exercised with respect to the Association's own confidential information. The Association will notify Principal Investigators and their institutions of any breach of the Association's physical or electronic security that may compromise the Confidential Information within 10 business days of its occurrence.
- E. Waiver of Obligations: The obligations governing the disclosure and use of Confidential Information do not apply with respect to Confidential Information that it can be demonstrated:
 - 1. was generally known to the public prior to submission of a grant funding request; or
 - 2. becomes generally known to the public through no unlawful or unauthorized act or omission by any recipient of Confidential Information, or in violation of a grant funding request; or
 - 3. was independently developed by any recipient prior to the effective date of a grant funding request; or
 - 4. was disclosed to a recipient by a third party who has the right to make such disclosure; or,
 - 5. was independently developed separate from any communication with or knowledge by the Association or the grants process.
- F. Subpoenas and Other Legal Proceedings: If any recipient of Confidential Information is requested to produce any of the Confidential Information pursuant to a legal or governmental proceeding, such recipient shall give the applicant or other owner of such Confidential Information (the "Discloser") as much prior notice of such request as is reasonably practicable under the circumstances and shall use reasonable efforts to assist the Discloser of such Confidential Information in objecting to such request. If a recipient is compelled to disclose any of the Confidential Information pursuant to such legal or governmental proceeding, such recipient shall use its reasonable efforts to assist Discloser in obtaining confidential treatment for such Confidential Information, will disclose only that portion of the Confidential Information which is responsive to the order, and will provide the Discloser with any copies of Confidential Information so disclosed; provided that such Confidential Information shall remain confidential until it falls into one of the categories specified above.
- G. Information Provided by Applicant: Applicants are required to complete a lay abstract suitable for use in public awareness and fundraising efforts, should the application be approved. Applicants accept all liability for ensuring that the information in the lay abstract contains no confidential or proprietary information.
- H. Disclosure Policy: The Association will not publicly disclose the names of investigators and/or project titles during the review process. After applicants have been notified of award decisions, the Association will publicly disclose only the names of investigator and/or project titles that have been approved for funding. This policy applies to all public communications by the Association, including communications with potential and current donors.
- I. Liability: The Association is a not-for-profit corporation, and does not have the financial resources to guarantee the confidentiality of information. The Association will take reasonable care to protect Confidential Information, but cannot be held liable for damages resulting from the accidental or wrongful disclosure of such information. Furthermore, members of the Association's Board of Directors, professional staff and Scientific Advisory Committee operate outside the Association's physical offices in Charlotte, NC. While these individuals sign Confidentiality Agreements, the Association cannot be held liable for damages resulting from the accidental or wrongful disclosure of such information by these individuals. By submitting a Letter of Intent, the applicant releases the Association and its agents, officers, directors and employees acting on its behalf, from any liability, loss, damage, costs, claims or causes of action arising out of the accidental, negligent or wrongful disclosure of confidential information.

VIII. Application Procedure

Applicants must successfully complete a seven-step process: 1. Letter of Intent; 2. Application; 3. Review of Research Grant Application; 4. Clarification/Revision (if required, as described); 5. Preliminary Approval; 6. Compliance; and, 7. Award.

Step 1. Letter of Intent: Following the issue of a Request for Applications (RFA), interested applicants may submit a Letter of Intent (LOI) in English using the Association-designated form and format. Investigators who submit LOIs by the stated deadline that describe projects determined to fall within the funding priorities and budgetary guidelines of the relevant RFA and meet all other eligibility guidelines will receive a written invitation to submit a Research Grant Application. Those investigators submitting LOIs deemed not to meet the stated objectives of the RFA or eligibility criteria will receive written notification from the Association of the disposition of their LOI.

Step 2. Application:

- a. Invitation: Only those investigators invited to submit a Research Grant Application will be eligible for review of their application.
- b. Form and Format: Investigators invited to submit full proposals must use the Association's Research Grant Application form and instructions, provided to investigators in electronic format. Application pages should be printed on one side in no smaller than 11 point font, with one-inch margins and consecutive page numbers. Applications that do not adhere to the form and format requirements specified on the grant application and in the instructions will not be evaluated. Original signatures on the Face Sheet (Form A) are required as part of the application package; submissions lacking this Face Sheet signed by the appropriate authorities will be returned without review.
- c. Deadline: The original and ten (10) hard copies of the complete grant application (including all required supporting documentation), in addition to the complete application formatted as a PDF file on a compact disc, must be received in the Association's office on or before the published deadline. A postmark by this date will not suffice; use of a delivery service with tracking and delivery confirmation is advised. The Association will not accept faxed or e-mailed copies of the completed application in place of paper copies. The Association will not grant deadline extensions under any circumstances.
- d. Expiration: All grant applications will be deemed to expire one year from the date submitted.
- e. Additional Guidance: Although investigators have discretion in designing studies, the Association encourages applicants to consider the Guidelines for Conducting CFS Research Studies provided by the Association at <http://www.cfids.org/profresources/grants-guidelines.asp> when developing protocols. All applicants are encouraged to review grant writing and grantsmanship information available at the NIH website <http://orwh.od.nih.gov/cfs/cfsFundingGW.html>.

Step 3. Review of Complete Application:

- a. Scientific Advisory Committee: A Scientific Advisory Committee (SAC) comprised of scientific peers will review grant applications based on scientific merit. Reviewers are selected based on the nature and scope of projects invited for full proposals. Names of appropriate reviewers are solicited with the Letter of Intent; however, the pool of reviewers is not limited to these recommendations from applicants.
- b. Conflicts of Interest: All reviewers will be required to identify potential conflicts of interest and to recuse themselves if a conflict appears or is deemed to exist. Further efforts will be made to avoid the following conflicts of interest in the review process:
 - i. Reviewers that are identified as collaborators, subcontractors and/or consultants with an investigator on any of the grant applications submitted under the same RFA;
 - ii. Reviewers from the same institution as any applicant in a given round, regardless of whether or not the prospective reviewer has had any involvement in preparing the application; or
 - iii. Reviewers who are otherwise deemed to be in a position to exploit a professional or official capacity in some way for their personal or corporate benefit.
- c. Other Advisory Bodies: At times, the Board of Directors may appoint other advisory bodies to provide guidance on matters of strategic importance relevant to the conduct of the overall research program. Such bodies may be subcommittees of the Board of Directors or may involve advisors outside the Board. In either case, the members of such bodies shall be bound by confidential policies described herein and shall make recommendations to the Executive Committee of the Board for the purpose of making award decisions. Applicants should refer to the Request for Applications for details specific to that cycle's review process.

Step 4. Clarification and Revision: In some cases, reviewers will identify aspects of the application or project that warrant further clarification to appropriately understand the investigator's plans. In other cases, remedies for certain limitations to the study may be identified by the reviewers. At the Executive Committee's

discretion, an applicant may be invited to revise the proposal based on such feedback from the review committee by a stated deadline. The Executive Committee, in consultation with the Scientific Director, will determine whether the revised proposal will be reviewed by the Scientific Advisory Committee or will be evaluated by the Executive Committee. This step in the process is reserved for those proposals with relatively minor limitations. Proposals requiring significant revision will be considered in the next funding cycle if revised and resubmitted by the Principal Investigator. If an applicant is invited to revise a proposal but does not meet the resubmission deadline, the proposal will be considered in the next funding cycle if the revised proposal is received by the appropriate deadline for that cycle.

Step 5. Preliminary Approval: The Association's Executive Committee makes all funding decisions, weighing heavily on the recommendations of the Scientific Advisory Committee and other advisory bodies appointed by the Board of Directors. Every effort will be made to provide written decisions about the outcome of the review to applicants within 10 weeks of the submission deadline. Applications not approved for funding will not be considered in the next funding cycle unless submitted again by the applicant. There is no appeal process for unfavorable decisions. Favorable funding decisions are conditional upon satisfaction of compliance requirements outlined in Step. 6., below.

Step 6. Compliance: Approved applicants will have 60 days from the date of preliminary approval notification to complete the initial compliance requirements outlined in the letter of preliminary award. Required documentation includes:

- a. Copies of the Agreement to Comply with Policies Governing the Award of Research Grants as signed by the Principal Investigator(s), all external collaborators, subcontractors, consultants and representatives from each institution;
- b. Copies of Institutional Review Board approvals and Animal Use polices reflecting the exact title of the approved study;
- c. Copies of the Principal Investigator's institutional policies that protect the privacy and confidentiality of study participants (including data encryption measures), ensure the security of all medical records and personal identifiers and identify action steps and corrective measures in the event of a breach of confidential study information and/or data.
- d. Copies of the Principal Investigator's institutional policies on fraud and conflict of interest;
- e. Letter signed by duly qualified officials representing any institutions indicating that intellectual property agreements among collaborators have been addressed and resolved (see Section XVII., below);
- f. Copies of all study instruments to be used in the conduct of the study; and,
- g. Letter from a duly qualified official representing any institution(s) from which the investigator receives support for the project approved for funding by the Association. Such letter should acknowledge Association support and clarify the non-duplication of funding (see Section XII., below).

If for any reason these requirements cannot be met within 60 days of the date of preliminary award, the Principal Investigators must submit a written plan for fulfilling the requirements within an additional 30-day extension. Principal investigators who do not fulfill the compliance requirements or submit such plan within 60 days of the preliminary award date will forfeit the preliminary approval and will no longer be considered for funding under the current cycle. Delays that extend beyond the 90-day deadline will be considered on a case-by-case basis, provided the Principal Investigator can demonstrate progress in the written plan submitted by the 60th day after the preliminary approval notification. If at any time more than 10 business days pass without a written reply to inquiries from the Scientific Director about progress toward meeting compliance requirements, preliminary funding approval will be forfeited. Proposals that fail to meet compliance requirements will not be considered in the next funding cycle unless re-submitted by the Principal Investigator.

Step 7. Award: Funding of successful applications that have fully met compliance requirements will commence on the first day of the month following completion of Step 6, but no earlier than the date requested on Form A of the research grant application. The letter of award will outline deadlines for written progress reports and payment dates. **All awards are contingent on continuous compliance with reporting requirements as outlined in these Policies.**

IX. Project Schedule

A projected schedule for each stage of the project from the time of award must be provided as part of the application. Steps should include, but are not limited to, Institutional Review Board approval, staffing, subject recruitment, sample evaluation, data analysis and publication. Milestones and performance measures should be incorporated in the project schedule submitted as part of the Research Plan (Form G of the application). Applications that do not include such a schedule and list of key milestones will result in administrative rejection of the entire proposal prior to peer review. If the proposal is approved for funding, this schedule will guide the Scientific Director's evaluation of progress as stated by the Principal Investigator in the required quarterly reports. Failure to make reasonable progress toward defined milestones may result in suspension of support (as described in Section XVI., below).

X. Uses of Funds

The funds awarded will be used solely for the purposes specified in the research application submitted to the Association and as approved in award documents or subsequently approved in writing by the Association.

- A. Exclusions: Association funds may not be applied to any portion of the following: expenditures by investigators for any purpose not approved in writing by the Association; expenditures above the amounts specified in the approved project budget; commitments made during the approved budget period which have not been paid within 60 days after the end of the budget period; or expenditures made before the starting date of the grant.
- B. Appropriate Expenses: Following is general information about the types of expenses that are supportable with Association grant funds. See the Instructions for Completing the Research Grant Application for additional detail on completing the budget section of the application.
 1. Personnel Costs: Salaries and fringe benefits of all personnel paid with Association grant funds must be consistent with those paid other employees of the grantee institution, regardless of the source of funds. Association funds are not intended or permitted to replace salaries already assured by institutional or other funds. Requests for salary costs of persons already employed full time by the applicant's institution or organization will be carefully scrutinized for appropriateness and need. In awarding grants, the Association does not assume any responsibility for the conduct of the investigation and/or the acts of the investigators since both are under the direction and control of the grantee institution and subject to its medical and scientific policies. Personnel compensated in full or in part with funds from an Association grant will not be considered to be employed by the Association, but to be employed by the grantee institution.
 2. Collaborators, Consultants and Subcontractors: Support for consultants and subcontractors are allowable uses of Association grant funds. The Principal Investigator is responsible for the conduct and compliance of all collaborators, consultants and subcontractors engaged in the conduct of Association-funded research by the Principal Investigator.
 - a. Collaborators are scientific and technical personnel from the grantee or other institutions participating in the research project without compensation. If one or more collaboration agreements are important to the completion of the project, a signed letter of agreement by each collaborator must be included with the grant application. Upon notification of preliminary award, all collaborators are required to sign the Agreement to Comply with the Policies Governing the Award of Research Grants, as stated in Section VIII., above.
 - b. Consultants are urgent, special, temporary or highly technical paid personnel who are not employees of the grantee institution and whose services are infrequent. Reimbursement of consultants with Association grant funds may occur only where such services are included in the original grant application budget. A signed letter of agreement from each consultant must be included with the application. Substitutions may be made only with advance, written approval from the Association's Scientific Director. Upon notification of preliminary award, all consultants are required to sign the Agreement to Comply with the Policies Governing the Award of Research Grants, as stated in Section VIII., above.
 - c. Subcontractors are paid scientific or technical personnel who are not employees of the grantee institution and whose services are needed for completion of the project. Reimbursement of subcontractors with Association grant funds may occur only where such services are included in the original grant application budget. A signed letter of commitment from each proposed

contractor, clearly stating the subcontract work scope, dates of performance and maximum costs, must be included with the application. Upon notification of preliminary award, all subcontractors are required to sign the Agreement to Comply with the Policies Governing the Award of Research Grants, as stated in Section VIII., above.

3. Consumable Supplies and Materials: Supplies and materials may include any type of laboratory supplies integral to the accomplishment of the approved research.
 4. Testing and Measures: The Association will not fund testing unless it is clearly related to the hypotheses and assesses the outcome measures outlined in the study design. Instruments may need to be modified to correct for the symptom overlap of CFS with other conditions, including affective disorders. Upon notification of preliminary award, copies of all testing instruments must be provided to the Association as stated in Section VIII., above.
 5. Patient Costs: Funds for hospitalization, professional medical services, travel or participant fees may be included in the grant budget. Justification must be provided that these funds are integral to the study and are not available from customary sources. The Association is concerned about the practice of requiring patients to pay for investigational procedures or treatments as part of a study protocol and will not fund studies that require said payment.
 6. Travel: Expenses for travel directly related to the activities and objectives of the Association-funded research project are permissible, provided that the expenses are included in the original grant application budget. Expenses related to participation in, or presentation at, scientific meetings are capped for each grant at \$1,000.
 7. Equipment and Fixed Assets: Equipment and fixed assets purchased with Association grant funds become the property of the grantee institution. See "Ownership of Equipment" (below) for further detail. However, investigators at large institutions and academic centers are encouraged to use resources, equipment and core facilities available to them. Indirect or institutional costs may not be charged for the costs of durable equipment and fixed assets.
 8. Other Direct Costs: Funds for all other direct expenses integral to the completion of the approved research project not otherwise specified in these Policies may be included in the grant budget. Occupancy costs can only be justified if implementation of the project requires renting facilities not available at the grantee institution; otherwise occupancy costs are factored into the indirect costs.
 9. Indirect Costs: Indirect costs for research grants may not exceed 10% of total direct costs. The grantee institution is expected to provide the required physical facilities, administrative services and other supporting services normally available in an institution. Since indirect costs are a function of direct costs, indirect costs may not be rebudgeted or applied to the purchase of fixed assets. In no case will the Association reimburse indirect costs that exceed 10% of direct costs. In the event of collaboration between multiple institutions, indirect costs are paid either to the Principal Investigator's institution as a percentage of total direct costs or one institution will be designated in the application as the administrative center and will receive and be responsible for distributing funds including indirect costs. In no case may the total of all indirect costs paid exceed 10% of the total of each award.
- C. Re-budgeting: At any time the Principal Investigator may make minor alterations up to 10% of the total award for direct costs to the allocation of the total award in the approved budget. Alterations greater than 10% may not be made without prior written approval from the Association's Scientific Director. When re-budgeting is necessary, the Principal Investigator should write to the Association's Scientific Director stating the reason for the re-budgeting, the categories to be debited and credited, the anticipated benefits to the project, why funds are available in the category to be debited, and why the need for the proposed changes could not have been foreseen at the time of initial application. The Principal Investigator must request approval within 30 days of discovering need for re-budgeting; the Scientific Director will respond to requests in writing within 30 days. Re-budgeting for amounts greater than 10% of the total direct costs award, without prior written approval from the Association's Scientific Director, or attempting to allocate more than 10% of the total award to indirect costs may lead to suspension or withdrawal of an award.
- D. Unexpended Funds: Any and all funds remaining at the conclusion of a research study must be returned to the Association within 30 days of the end of the approved budget period, unless renewal or extension of support has already been approved in writing by the Association (as described in Section XIII., below). If renewal support is approved, unexpended funds will be applied to the payment of the renewal grant.

XI. Ownership of Equipment

Equipment purchased with Association grant funds will be under the direction and control of the study's Principal Investigator. Title to such equipment will be vested conditionally in the grantee institution during the active period of the grant. At the conclusion of the grant period, title will be vested in full to the grantee institution.

In the event a grant is transferred to another institution and equipment purchased with Association funds is movable and necessary for continuation of the Association-funded research study, it is the Association's intent that this equipment will be transferred with the grant. If it becomes necessary to transfer equipment to another institution for any reason, a written request and rationale must be submitted to the Association's Scientific Director within 30 days. Notice of the Association's decision on such a request will be provided in writing to the Principal Investigator within 30 days of the receipt of the request. Title to such equipment then will be vested conditionally in the new grantee institution, while title to remaining equipment, if any, will be vested fully in the original institution. Unless otherwise specified and approved in writing by the Association, Association grant funds may not be used to move or relocate equipment from one institution to another.

XII. Other Support

While not offered in duplication of other support, Association support may be used to supplement other sources of support. Accurate information from the investigator and grantee institution about other support is crucial to the review of applications and the continued support of any Association award. Upon award of an Association grant, a letter from an official representing any institution(s) providing support to the investigator must acknowledge Association support and clarify the non-duplication of funds (as described in Section VIII., above). If supplemental support follows an Association award, such letter must be provided to the Association's Scientific Director within 60 days of the supplemental award. Failure to provide complete and accurate information may be construed as an attempt to mislead the Association and could lead to an application not being reviewed or an award being withdrawn.

XIII. Continuing Support

- A. Commitment: Grants are approved for a maximum of 18 months. No grant will be automatically renewed or extended.
- B. Extension of Term: The Association expects principal investigators to fully complete research grant studies within the time period allotted for the total original award. If for some unexpected or unusual reason the Principal Investigator needs additional time to complete the study, an extension of the term of a grant *without additional funds* may be requested in writing. A request for an extension of term must include: (1) the requested term of the extension, (2) an explanation of why the research study was not completed and the funds were not expended in the allotted time, (3) the amount of money to be carried forward into the extension period, (4) a report on the research progress and budget to date, (5) a statement of what research will occur, (6) how original project milestones will be met under the revised schedule, and (7) how the funds will be used during the extension period. No extension of term may exceed six months. Decisions on requests for extension of term will be made by the Executive Committee of the Board of Directors, and will be communicated to the investigator in writing no later than 45 days after the request is received by the Association.
- C. Renewal or Continuation Requests: Financial support beyond the term of the original grant will require submission of a new proposal during the next funding cycle. Data accumulated from the original grant proposal can be used as preliminary data to support subsequent grant applications. All proposals are considered new submissions, are competitively reviewed and will follow the review process in force at that time.
- D. New Requests from Current Grantees: Grantees receiving current support from the Association are permitted to apply for funding for new studies. To be eligible for consideration, the grantee must be compliant with all reporting and other compliance requirements of the funded grant. See Section XVIII., below, for information about the required reports.

XIV. Research Involving Human Subjects or Animals

The Association requires that all research studies involving human subjects be approved by the Institutional Review Board (IRB) of the grantee organization. Written confirmation of approval by the IRB is required before funding of an approved research study can commence, as outlined in Section VIII., above.

For research involving animals, written approval from the Institutional Animal Use and Care Committee must be submitted to the Association prior to the commencement of funding, as outlined in Section VIII., above.

XV. Transfer of a Grant

- A. Requested Transfer: Transfers of grants to other institutions are not routinely granted and are made at the discretion of the Association's Executive Committee. In the event that a Principal Investigator requests the transfer of an approved grant, whether or not funding has commenced, the Principal Investigator should submit the following: (1) a written request for approval of the grant transfer to another institution, expressly noting the requested termination date of the original award; (2) a detailed report of expenditures prior to the date of the transfer request, including a listing of any equipment that is to be transferred (see also Section XI., above); (3) a letter from the original grantee institution attesting its willingness to relinquish the grant and return any unexpended funds to the Association; (4) a letter from the proposed new grantee institution attesting its willingness to accept and administer the grant; (5) a new grant cover page and budget completed by the new grantee institution; (6) a revised project schedule, adhering to the original term of award; (7) written approval from the new institution's Institutional Review Board and/or Animal Care and Use Committee for research involving human or animal subjects; and (8) written agreement to comply with the Policies Governing the Award of Research Grants signed by the Principal Investigator and an authorized official of the new institution.

Written approval of any grant transfer will be sent to the Principal Investigator by the Association's Scientific Director within 45 days of the request. Payments to the new grantee institution will not be initiated until a financial report has been received from the prior grantee institution. Unexpended funds returned to the Association will be transferred to the new grantee institution.

- B. Incapacitation: In the event the Principal Investigator is unable to continue supervising a grant, whether due to extended illness, incapacitation, death or other reason, in most cases the grant will be terminated. Written notice must be provided to the Association within 30 days of the date of any incapacitation, whether temporary or permanent, that lasts 30 days or more. If the grant is terminated, no obligations incurred after the incapacitation date will be reimbursed. Any unexpended funds must be returned to the Association with a final financial report within 30 days of the termination date.

In some cases the Association will approve the transfer of a grant to a new Principal Investigator qualified to continue the study. Applications for such a transfer must be submitted in writing by the original Principal Investigator or an authorized official of the grantee institution, must include a rationale to support the new Principal Investigator's credentials for leading the study, and the new Principal Investigator's CV and bibliography. Transfers are not routinely granted and are made at the discretion of the Association's Executive Committee. Funding will be suspended during the time in which the proposed Principal Investigator's qualifications are being reviewed. A written response to the request for transfer to a new Principal Investigator will be made within 45 days of its receipt by the Association. If the transfer is not approved, the Association will terminate the grant and all unexpended funds must be returned to the Association within 30 days.

XVI. Termination of Grant

- A. Voluntary Termination: In the event a grantee institution or investigator wishes to relinquish an Association grant prior to the end of the grant period, written notice to the Association is required. The notification should be signed by the Principal Investigator and by an authorized official of the grantee institution. No obligations incurred after the termination date will be reimbursed and any unexpended funds must be

returned to the Association with a final financial report within 30 days. A detailed report describing the results generated up to the time of termination will be required (see also Section XVIII., below).

- B. **Withdrawal of Grant:** The Association reserves the right to withdraw a grant if it is found that the Principal Investigator has engaged in scientific fraud or that information contained in the application is incorrect and intended to mislead the Association, its Scientific Advisory Committee or its Board of Directors. Failure to comply with these Policies, including reporting requirements, is also cause for withdrawal of support. Repeated or prolonged delinquency in fulfilling the reporting requirements or making progress toward stated project milestones may result in withdrawal of the grant. In the event the Association decides to withdraw support, the Association will provide written notice of such decision to the Principal Investigator and the grantee institution within 15 days. No obligations incurred after the termination date will be reimbursed and any unexpended funds must be returned to the Association with a final financial report within 30 days. A detailed report describing the results generated up to the time of termination will be required (see also Section XVIII., below). There is no appeal process for a decision to withdraw support.

XVII. Intellectual Property and Data Sharing

- A. **Availability of Data and Resources:** The Association is a public charity and research conducted with funds from the Association is conducted in the public interest. The sharing of research resources directly affects the pace and cost of future research. Accordingly, the Association requires that research resources generated under Association-funded grants will be shared with other qualified researchers working on CFS. These resources include, but are not limited to, biological specimens or reagents, data sets and measurement scales. The Association requires that the Principal Investigator and the grantee institution accept the responsibility for providing resources developed during the course of Association-sponsored research to investigators who request them, allowing sufficient time for the original investigators to profit from their efforts. Reasonable costs, such as photocopying, packaging, mailing, etc., may be charged to the requesting investigator. Grantees agree to cooperate and collaborate with the Association and other researchers and to share access to results on fair and reasonable terms no later than 12 months after either the date of the grant expiration or the date on which IRB approval ends, whichever comes first. Submission of an application for funding constitutes confirmation that there are no known requirements that would prohibit, delay or restrict the ability to share results from the proposed study, including requirements of third-party collaborators or companies with which the investigator or institution are affiliated.
- B. **Intellectual Property Agreements among Collaborators:** Although the Association does not specify when intellectual property negotiations must take place among researchers funded under this program, the Association does require that collaborators agree on any material intellectual property issues prior to submission of the grant application. Applicants are required to include a letter indicating that intellectual property agreements among collaborators have been addressed and resolved before any final funding commitments can be made (see Section VIII., above).
- C. **Patents:** The Association acknowledges that any discoveries made by researchers through Association supported research are the property of those conducting and responsible for the research and that unless otherwise agreed to by the parties, such researchers have the first opportunity to exploit the research commercially or otherwise. However, it is the Association's intent that potentially beneficial discoveries be developed to make such discoveries available to the public. Association grants are made with the understanding that patentable discoveries made in the course of Association-sponsored research will be pursued by the grantee.
1. Unless otherwise indicated or requested by the grantee institution, title to any invention or discovery shall reside in the grantee institution. All inventions and discoveries made with the support, in whole or in part, of Association grant funds must be reported to the Association as part of the required quarterly or post-grant reporting process. The Association defers to the patent policies of the grantee institution.
 2. No patent or patent application on an invention or discovery supported in whole or in part by Association funds shall be abandoned without first notifying the Association and giving the Association the opportunity to take title to the patent or patent application at its own expense.
 3. If a grantee institution has no existing patent policy or procedure for administering inventions as of the date of the notice of final award; or if a grantee institution's policy or procedure for

administering inventions has lapsed as of this date, the Association shall have the right to determine the disposition of invention rights.

D. Publication:

1. The Association requires that a manuscript detailing the results of Association-funded research be submitted for publication no later than 12 months after the expiration of the grant, in the open scientific literature indexed for MEDLINE, consistent with high standards of scientific excellence and rigor. Any manuscript must include acknowledgement of the funding provided by the Association by stating; "This work was supported (in whole/in part) by a grant from the CFIDS Association of America." The Association retains the right to publish reports of detailed results of Association-funded research in its print and electronic publications after the results have been published in the peer-reviewed literature. Grantees are required to provide the Association with five hardcopy reprints or a PDF file of each publication of results of Association-funded research. Grantees are expected to assist the Association in efforts to publicize the results of published research by participating in media interviews.
2. If no scientific manuscript describing the results of the funded study is submitted for publication within 12 months of the date of expiration of the grant, the Association reserves the right to facilitate publication by other means, including through its own print and electronic publications.

- E. Scientific Presentations: Acknowledgement of financial support by the Association should accompany all publicly presented research. Grantees are expected to notify the Association when any presentation using data generated with Association funding has been accepted by the sponsoring institution of such presentation. Copies of acceptance notifications, abstracts, slides and other materials must be included in the required quarterly and post-grant reports. The Association would be grateful for notification of presentations or publications that occur after the term of the grant and fulfillment of all grant-related reporting and compliance requirements.

XVIII. Reporting Requirements

A. Quarterly Reports:

1. Grantees are required to submit written quarterly reports of the funded study's progress to the Association's Scientific Director according to the schedule that is outlined in the final letter of award (see Section VIII., above). Failure to submit quarterly reports by those deadlines will result in suspension of quarterly grant disbursements until reports are received. Repeated or prolonged delinquency in reporting may result in suspension or withdrawal of support (see Section XVI., above).
2. Quarterly reports should include: (a) documentation of progress toward or achievement of the milestones and performance measures described in the approved application; (b) a comprehensive technical report on research progress accomplished according to the established project timeline; (c) explanation of any departures from the established project timeline; (d) copies of publications or presentations on the funded research occurring during the quarter. All information contained in the quarterly report that has not been published in a peer-reviewed journal or communicated in an educational forum is considered confidential and the Association will take reasonable care to protect the information (see Section VII., above). As stated in Sections IX. and XVI., above, failure to make reasonable progress toward milestones defined in the project schedule may result in suspension or withdrawal of support.

- B. Meetings and Site Visits: The Association's Scientific Director may request a site visit or conference call to discuss information contained in interim progress reports and general progress toward stated project milestones. Every effort will be made to accommodate the investigator's schedule in scheduling such meetings; however, refusal or failure to accommodate a request within a reasonable timeframe may be cause for suspension or withdrawal of support.

- C. Post-Grant Report: Grantees are required to submit a post-grant report within 90 days of the termination of the grant period, including grants that terminate as a result of the incapacitation, death or transfer of the Principal Investigator, or by relinquishment. Post-grant reports must be completed on the Association forms provided to the Principal Investigator prior to the conclusion of the grant period. The report must include the following:

1. A comprehensive technical report (or a manuscript intended for publication) on the research accomplished;
2. A 200-word summary of the technical report in layperson's language;
3. Plans for publication and presentation of the results of the funded research; and
4. A financial report on the use of Association funds, as described below.

All information contained in the post-grant report that has not been published in a peer-reviewed journal or communicated in an educational forum is considered confidential and the Association will take reasonable care to protect the information (see Section VII., above).


D. Financial Reports:

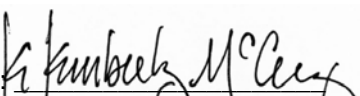
1. Grantee institutions are required to provide the Association with a complete accounting of the use of Association grant funds every six months following the commencement of funding and within 90 days after the termination of the grant period. The accounting report should utilize the same expense categories as the original application and should compare budgeted figures with actual expenditures. A separate accounting must be maintained for Association grants by the applicant institution. This accounting, substantiated by invoices and payrolls, must be provided to the Association upon request as documentation of the expenses described in the financial reports submitted as a condition of support.
2. If an investigator is applying for a new or renewal research grant, a financial report for current grants must be submitted with the new application by the specified deadline for the application. The Association will be unable to consider a new or renewal request without a completed report of sufficient detail to document that funds used were dedicated to the conduct of the study as approved.

XIX. Approval and Revision of Policies

These policies are reviewed at least annually. Changes are approved by the Executive Committee of the Association's Board of Directors. Funded Principal Investigators and the authorized representatives of their institutions will be sent by electronic mail updated copies of these policies if they are revised during the period of performance and any period following the end of the period of performance during which reporting or other compliance requirements are still being fulfilled by the Principal Investigator. The revised policies will be binding upon all parties to the grant unless written concerns are registered within 30 days of the date of transmittal of the revised policies. The Association's Executive Committee retains the sole authority to address and mitigate questions and concerns about approved Policies.

These Policies Governing the Award of Research Grants have been approved by the Executive Committee of the CFIDS Association Board of Directors:

Signed: 
 Susan Jacobs, Esquire
 Secretary, Board of Directors
 May 29, 2008

Signed: 
 K. Kimberly McCleary
 President & Chief Executive Officer
 May 29, 2008

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