

The CFIDS Association of America

Policies Governing the Award of Research Grants as of July 8, 2011

This document outlines the CFIDS Association of America's policies, practices and expectations for administering its research grants program. It is intended to provide all interested parties with information about their respective rights and responsibilities. Over nearly 25 years of supporting research, we have found that the most productive relationships with grantees are based on shared goals and mutual trust, and we strive to cultivate a positive experience with applicants and grantees in furtherance of our mission to make CFS widely understood, diagnosable, curable and preventable.

The CFIDS Association is committed to ensuring that the outputs of the research it funds accrue to the public benefit. This is important to donors who financially support the organization, participants in the research, the larger community of people affected by CFS, and the general advancement of biomedical research. We have developed these policies as a means to maximize the value of our sponsored research program that includes the SolveCFS BioBank, as well as the individual projects we support. They are based on best practices across a wide array of innovative, ethical, conscientious and lawful organizations engaged in patient-centered research and scientific discovery.

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 our 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 a 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 and SolveCFS BioBank

Since its founding in 1987, the CFIDS Association of America ("Association") has supported research into the biological basis of chronic fatigue syndrome (CFS) through direct grants to investigators, sponsored scientific symposia and meetings, fostered collaborations and, most recently, established the SolveCFS BioBank (described below). CFS has received increasing attention from the scientific and general media, generating both increased interest and unprecedented opportunities for progress.

To meet the unequivocal need for a more robust scientific enterprise for CFS, in late 2007 the 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 Association's research program is to build, support and link a critical mass of innovative and credible researchers focused on early detection, objective diagnosis and effective treatment and to create, identify and leverage new private and commercial funding sources and opportunities for CFS investigators.

In March 2010, we launched the SolveCFS BioBank to create the first integrated clinical registry and biorepository for CFS. The SolveCFS BioBank utilizes a cooperative biobanking structure as part of the Genetic Alliance BioBank. Subjects, including individuals diagnosed with CFS by a physician, healthy individuals and contact and noncontact controls, consent to participation in the SolveCFS BioBank, provide responses to standardized and validated instruments and agree to provide biological samples. A unique feature of the SolveCFS BioBank is that participants can be recontacted to obtain longitudinal data, respond to new questionnaires and provide additional biological specimens. Researchers who wish to utilize assets of the SolveCFS BioBank are required to submit a detailed description of the information or type of sample needed to successfully complete the project. If the project is proposed in response to an Association-issued Request for Applications (RFA), the proposal should follow the

application process outlined in the RFA. Costs for BioBank data or samples must be included within the proposed budget. (See Section X, below.) The review of such proposals will follow the process outlined in the RFA and these policies. If the project is supported by a source of funds other than Association-awarded grants, the principal investigator should contact the Association's Scientific Director for details on the application and approval process. (See contact information at the end of these policies.)

The CFIDS Association requests investigators to encourage study subjects to enroll in the SolveCFS BioBank. Enrollment in the SolveCFS BioBank facilitates a "virtual center" through which well-characterized subjects' data and samples can be interrogated by approved investigators who approach CFS from multiple scientific and clinical perspectives. The costs associated with an individual's enrollment in the SolveCFS BioBank (including the process of obtaining informed consent) are borne by the Association, not the subject or the investigator.

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 direct support for scientific research on CFS. Funding decisions rest with the Executive Committee of the Board of Directors of the Association, acting upon the recommendations of peer reviewers, who evaluate the scientific and strategic merits 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. The policy of the organization is to fund only those projects for which it has raised sufficient funds. An award letter constitutes a secured pledge to support a specific project, according to the terms of these policies.

Periodically the Association receives donations earmarked for particular research projects or a particular researcher. 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 and commercial institutions with no restrictions as to geographic location.
- B. Agencies: Federal and state government agencies (within the United States and in other countries) 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. For proposals involving postdoctoral fellowships 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 and professional staff 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 and staff 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 peer reviewers 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 peer reviewers 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. Submission of an application is deemed to be acceptance of these provisions.

VIII. Application Procedure

Applicants must successfully complete the six-step process described below:

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 full proposal. 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 full proposal 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 no less than half-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 nine (9) additional 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 Trans-NIH ME/CFS Working Group website <http://orwh.od.nih.gov/CSF%202011/resources.htm>.

Step 3. Review of Complete Application:

- a. **Peer review:** Peer reviewers 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 peer 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 authorize 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.

Step 4. Preliminary Approval: The Association's Executive Committee makes all funding decisions, weighing heavily on the recommendations of the peer review of factors related to scientific and strategic merit. Upon submission of a full proposal, applicants will be informed in writing of the date by which they can expect to receive notification about the outcome of the review, the date of which will be within 10 business days of the conclusion of the review process. 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. 5., below.

Step 5. 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 and a duly qualified representative from his or her respective 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. A list 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).
- h. For studies that utilize assets of the SolveCFS BioBank, a signed copy of the Uniform Biological Material Transfer Agreement (UBMA) (available at <http://www.ott.nih.gov/NewPages/UBMTA.pdf>).

If for any reason these requirements cannot be met within 60 days of the date of preliminary award, the Principal Investigator must submit a written plan for fulfilling the requirements within an additional 30-day extension. Those 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 6. 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 collection, processing and 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. The Principal Investigator's signature of the Agreement to Comply with the Policies Governing the Award of Research

Grants, as stated in Section VIII., above constitutes agreement from all the collaborators and their respective institutions with the terms of the award.

- 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. The Principal Investigator's signature of the Agreement to Comply with the Policies Governing the Award of Research Grants, as stated in Section VIII., above constitutes agreement from all the consultants and their respective institutions with the terms of the award.
 - 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. The Principal Investigator's signature of the Agreement to Comply with the Policies Governing the Award of Research Grants, as stated in Section VIII., above constitutes agreement from all the subcontractors and their respective institutions with the terms of the award.
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. Solve BioBank Samples and/or Subject Data: The Association encourages the use of data and samples collected through the SolveCFS BioBank. Costs for such data and samples must be included in the grant budget. To determine associated biobank costs in developing his/her proposal, the applicant will submit Form J to the Association's Scientific Director no later than 30 days before the stated deadline for full applications. The specifications of data and/or samples required for completion of the project will be confirmed with the applicant and compared to existing resources. If custom sample collection/processing or additional subject recruitment is required, a timeline reflecting those action steps by the Association will be provided to the applicant. Within 10 business days the applicant will also be provided with a cost quotation for the data and samples, according to the specifications provided by the applicant. If for any reason an estimate cannot be provided within 10 business days, the applicant will be granted an extension. These costs must be reflected in the grant budget, within the maximum award amount. **NOTE: Applicants who plan to utilize BioBank assets are encouraged to submit Form J as early in the application process as possible.**

Applicants who propose using SolveCFS BioBank assets but who do not submit a request for cost/timeline estimate at least 30 days before the deadline for full applications will result in administrative rejection of the entire proposal prior to peer review. Similarly, proposals that do not reflect the costs and time estimate provided by the Association will result in administrative rejection of the entire proposal prior to peer review.

If an application proposing use of SolveCFS BioBank assets is approved for funding, the timeline and cost quotations provided by the Association at the time of application will be verified and details (including material transfer agreement) will be finalized during the Compliance step (described above in Section VIII., above).

7. 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.

8. **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.
 9. **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.
 10. **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. The investigator's performance under all past Association grants will be considered in the review of any new proposal. Performance will include compliance with policies in force during the grant period(s) under which the investigator was funded (including steady progress toward and completion of project milestones outlined in the approved applications); publications and/or new awards from other institutions arising from Association-funded research; and active engagement to advance understanding, diagnosis and treatment of CFS.
- 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. The investigator's performance (as described above) under all past Association grants will be considered in the review of any new proposal.

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. Studies that utilize assets of the SolveCFS BioBank, collected under approval from the Genetic Alliance BioBank IRB, should consult with their own institution's IRB the need for or exemption from additional IRB approval. Copies of the Genetic Alliance IRB approval for the SolveCFS BioBank are available to applicants and awardees upon request.

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. Data Sharing and Intellectual Property

- 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. The Association expects all of its grantees to maximize the availability of research data with as few restrictions as possible. The Association will foster an environment that enables researchers to maximize the value of research data. Specifically, we will work in partnership with others to ensure that key data resources are developed and maintained for use by the research community; recognize the contributions of researchers who generate, preserve and share key research datasets; and contribute to best practices for data sharing in different fields, recognizing that different data types raise distinct issues and challenges. All those seeking funding from the Association should consider their approach for managing and sharing data and resources at the research proposal stage and requires that applicants submit a data-sharing plan as part of the full proposal. (See Form H.)
- B. **Data Standards:** The Association has partnered with the NIH, CDC and a consortium of academic and clinical researchers to develop consensus on standard instruments and operating procedures for use in CFS research. If consensus is reached by the time of awards arising from the 2011 RFA, the Association will recommend use of these standard instruments and operating procedures to funded investigators.
- C. **Data Repository:** The Association is presently working to establish a secure bioinformatics platform for scientific collaboration and data-sharing that enables the effective communication of detailed research data, tools, and supporting documentation. It is anticipated that this platform will be in place by the date that awards resulting from the April 6, 2011 Request for Applications are made. As envisioned, this platform will link data across research projects through use of a global unique identifier (GUID) and related data dictionary. Investigators funded under this RFA would be able to use these technologies to submit and access data. Applicants will be updated with additional details about the platform as it is developed.
- D. **Intellectual Property Agreements among Collaborators:** Although the Association does not specify when intellectual property negotiations must take place among grantees 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). Agreements among the collaborators and their respective institutions must be consistent with policies described below.
- E. **Materials:** Tangible research materials which are unique and substantial outputs created in the course of performing the funded research shall be made available to other researchers, subject to the existence of available quantities, under either the PHS Simple Letter Agreement (SLA) (available at <http://www.ott.nih.gov/pdfs/slaform.pdf> for the Uniform Biological Material Transfer Agreement (UBMA) (available at <http://www.ott.nih.gov/NewPages/UBMTA.pdf>) to investigators at non-profit or academic institutions.

When reasonable, the grantee should consider deposit of the materials in an appropriate repository under the above MTAs or terms which are no less restrictive. For avoidance of doubt, the standard MTAs used by ATCC and Jackson Laboratories shall be deemed to be compliant with this requirement. In addition, the grantee is encouraged to offer such materials to for-profit entities under any version of the Science Commons MTAs (available at <http://mta.sciencecommons.org>).

The grantee may satisfy the above requirement with respect to for-profit or non-profit transfers of materials, or both, by offering to provide materials without any binding MTA or other agreement. If any materials are subject to third party rights, including patents or contractual obligations, and such third party rights would interfere with the grantee's ability to comply with the above requirement, then the grantee shall promptly inform the Association upon becoming aware of such requirement. If third party patent rights would be violated by the distribution of the materials, then the Association shall grant to the grantee a waiver to the

extent necessary to avoid infringement. If the grantee's compliance with the above requirement would violate a contractual obligation, then the grantor shall grant a waiver to the extent such obligation was entered into in good faith and not for the purpose of circumventing the Agreement to Comply with Policies Governing the Award of Research Grants.

The foregoing obligation may also be met by depositing the materials in any applicable third party material repository that makes such materials available to the public under the terms and conditions stated above.

- F. 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. The grantee and his/her institution shall notify the Association of any purported inventions for which the grantee and his/her institution determines not to prosecute or maintain patent activity within 60 days of such decision (and for decisions not to maintain, reasonably in advance of the due date for any required maintenance payment). In such case, the Association may prosecute or maintain any patent activity and control the licensing and/or other exploitation of resultant patent rights in the invention at its own cost, and all income with respect to such activity by the Association will inure to the sole benefit of the Association.
 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.
- G. Licenses: The grantee and his/her institution retain the right to use, and non-exclusively license to other not-for-profit institutions the right to use, the inventions solely for internal and educational non-commercial purposes, including sponsored research. The grantee and his/her institution will grant to the Association a worldwide, fully paid-up, royalty-free, perpetual license under the inventions (including all patent and other intellectual property rights therein), to make, use, practice any method, process or procedure within the inventions for educational and non-commercial research use and to sublicense such inventions to any Association-funded researcher.
- H. Distribution of Income: If the grantee and his/her institution are successful in licensing inventions resulting from the an Association-funded grant then the grantee and his/her institution agree to share any net income with the Association in proportion to the grant funding provided by the Association that resulted in the invention, as determined by the original invention disclosure. Net income shall mean all income received by the grantee and his/her institution resulting from a license less the direct, documented costs incurred by the grantee and his/her institution to perfect its interests in the invention.
- I. 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.
3. A copy of any scholarly articles describing the funded research project shall be deposited in PubMed Central not later than six (6) months from the date of first publication in a journal. Such articles shall be licensed to the public under a CC-BY 3.0 license available at <http://creativecommons.org/licenses/by/3.0/>. Grantee may comply with the above requirement by publishing such article in a journal with a policy consistent with the above requirement, or by retaining sufficient rights to comply with this requirement.
4. All data supporting the publication shall be made available for download from a digital repository under terms and conditions no more restrictive than the Science Commons Protocol for Implementing Open Access Data (<http://sciencecommons.org/projects/publishing/open-access-data-protocol/>), upon:
 - i. Six (6) months after any publication describing the results of the funded research project;
 - ii. Twelve (12) months after the completion of the research project; or
 - iii. Twelve (12) months after the expiration or termination of the Agreement to Comply with Policies Governing the Award of Research Grants,

whichever is earliest, and subject to any reasonable delay necessary to evaluate for patentability and to file any patent applications. Grantee may comply with the above requirement either by:

- i. Depositing a copy of the data in a third party digital repository from which it may be downloaded free of charge, or
 - ii. Offer such data for download on a Website without charge, or
 - iii. Offer to distribute such data on any medium which is commonly used, subject to a reasonable charge for the cost of reproduction and distribution.
 5. In addition, the grantee shall notify the Association in writing that data has been deposited.
- J. 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 will conduct a site visit once an award has been made to verify that resources are in place for study to be conducted in the award period. Other such site visits will be scheduled at the mutual agreement of the Scientific Director, principal investigator and other key study personnel. Every effort will be made to accommodate the Principal Investigator's schedule in arranging 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 biannually. 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.

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