For application technical support, please contact nappleton@cff.org

Program Name: 2023 Screening Improvement Program (SIP) Award for Optimizing the Diagnosis of Infants

Brief Program Overview/Description: The purpose of the SIP mechanism is to catalyze efforts aimed at improving the screening system used for early diagnosis. This Request for Applications (RFA) is focused on improving equity and expediting the early diagnosis of CF through uniformly accelerated Newborn Screening (NBS) that includes as a priority addressing the special needs of the diverse populations of US infants. However, this RFA is not intended to support projects devoted to clinical trials/interventions.

Funding Amount: Applicants may request up to $75,000 per year for two (2) years, plus an additional twelve (12) percent of indirect costs may be requested per year. Refer to Section III. below for further details regarding funding options.

Eligibility:

- The applicant institution **must** have at least one Cystic Fibrosis Foundation-accredited Center or Affiliate program as a partner.
- Quality improvement methodology must be incorporated into the proposal.
- Candidates must be U.S. citizens or U.S. permanent residents (must have obtained permanent residency prior to the time of application)
- Applicants must be actively engaged in CF NBS programs and involved in the second, third, and fourth components listed in Section IV. below.
- *Additional eligibility requirements can be found in Section IV below.*

Key Dates:

Published	May 12, 2023
Full Application Deadline	**July 10, 2023***
Committee Review	September 2023
Notification to Applicants	October 2023
Earliest Project Start Date	December 1, 2023

Table of Contents:

*We highly encourage all applicants to pre-register their profile, institution, contacts, and Title of their application at least two weeks prior to the application deadline. This will help to ensure the CFF Grants & Contracts Management and Administration (GCMA) Office is able to assist all applicants with any potential system-related queries prior to the Application Deadline.

I. About the Cystic Fibrosis Foundation

The mission of the Cystic Fibrosis Foundation is to cure cystic fibrosis and to provide all people with CF the opportunity to lead long, fulfilling lives by funding research and drug development, partnering with the CF community, and advancing high-quality, specialized care.

To achieve this mission, various types of grants and awards are offered to support meritorious research in CF.

II. Program and Award Overview

The overall purpose of the Screening Improvement Program (SIP) is to catalyze efforts aimed at improving the screening system used for early diagnosis. This Request for Applications (RFA) is focused on improving equity and expediting the early diagnosis of CF through uniformly accelerated Newborn Screening (NBS) that includes as a priority addressing the special needs of the diverse populations of US infants. However, this RFA is not intended to support projects devoted to clinical trials/interventions.

Newborn screening programs are organized as population-based public health services applying preventive medicine principles in defined regions to reduce morbidity and mortality from genetic disorders by pre-symptomatic detection of risk using dried blood specimens from newborns analyzed in central laboratories that are linked to clinical follow-up programs for diagnosis and rapid institution of specialized therapies. The organization of NBS programs features a system of care that includes education, the screening test(s) per se, follow-up, diagnosis, evaluation/management, and quality assurance. After demonstration of benefits and endorsement by both CDC and the CFF, the implementation of CF NBS during 2006-2009 throughout the USA provided many new opportunities for enhanced care, teaching, and research, but also occurred with such relative rapidity that a need for nationwide quality improvement became apparent during the past decade. Of special concern, research results suggest that the wide range of CF NBS algorithms and follow-up programs has failed to achieve equity and consistent timeliness for all patients. Many states are not using best practices to ensure that the 20% of minorities being diagnosed, as well as other categories of children with CF, are receiving equal opportunities for early diagnosis and treatment. It is also clear that the unacceptably large number of missed cases due to false negative screening results needs to be reduced. In addition, survey data revealed that about half of the families with positive CF screening results revealing a pathogenic CFTR variant do not receive genetic counseling. Consequently, the CFF developed a Screening Improvement Program for Optimizing the Diagnosis of Infants.

The NBS system involves a sequence of procedures that begins with collection of dried blood spot specimens on filter paper cards, which is usually accomplished in the birthing hospital at 2-3 days of age and requires meticulous attention to specimen quality; a second specimen will be needed when the initial blood spots are unsatisfactory, and this causes preventable delays. The dried blood spot specimens are then sent to a regional NBS laboratory, which is typically the state's public health lab, where the analyses are either partially or completely performed in a protocol that begins with measurement of immunoreactive trypinsinogen (IRT) and, if "high," a DNA analysis for CFTR mutations— ideally completed during a baby's first week of life. The IRT biomarker is a challenging analyte because of its lability and the impact of marked immunoassay performance variations over time that complicate setting cutoff values— leading the Association of Public Health Laboratories to recommend floating cutoffs at a specified percentile; however, about half the states are currently using use a fixed IRT cutoff value. Twelve states use a 2-sample screening system that requires a repeat blood specimen at about 2 weeks of age and may lead to delays. Some states are clustered together in an arrangement by which a regional lab applies its algorithm to contracted states that send specimens— another step that can cause delays. In addition, five regions rely on a vendor that uses a different algorithm for each client. In some regions, a biomarker test is done in one site and a DNA analysis elsewhere. For positive screening results, a follow-up assessment needs to be organized through provider/parent communications, scheduling of a sweat test, and a diagnostic evaluation of the screen-positive infant with successful sweat testing.

In the complex sequence summarized above, there are many possibilities for inequitable operations, delays, and missed cases. Observations have shown that delays can occur in the dried blood specimen collection and/or transfer steps, in the laboratory analyses, in the procurement/transfer of second blood specimens, in the communications processes, and in scheduling and successful completion of sweat tests. Thus, timeliness of diagnosing CF through efficient, equitable NBS can be challenging. Although guidelines for CF NBS published by the Clinical and Laboratory Standards Institute state that the goal is for all infants with CF to be diagnosed and integrated into clinical care systems at CF clinics by 2-3 weeks of age, data stored in the CFF Patient Registry have revealed that many states are experiencing delays and not routinely diagnosing CF through NBS during the neonatal period, i.e., the first 28 days of life. The CFF believes that the timeliness aspect of this care delivery challenge, improvements in equity, and all the other components of the NBS system can be enhanced by quality improvement projects.

Applicants are encouraged to refer to The Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) revised publication guidelines found at http://qualitysafety.bmj.com/content/qhc/25/12/986.full.pdf to see what is required for work on QI-focused projects to be published.

III. Funding Amounts

Applicants may request up to $75,000 per year for two (2) years, plus an additional twelve (12) percent of indirect costs may be requested per year for multi-center SIP applications to stimulate collaborations within states proposing algorithm transformation to best practices such as floating IRT cutoff values and/or expanded *CFTR* panels.

IV. Eligibility

- Candidates must be U.S. citizens or U.S. permanent residents (must have obtained permanent residency prior to the time of application)
- Applicants must be actively engaged in CF NBS programs and involved in the second, third, and fourth components listed below:
  1) Education of professionals and parents
  2) Screening, i.e., specimen collection, submission, and testing
  3) Follow-up of abnormal and unsatisfactory test results
  4) Confirmatory testing and diagnosis
  5) Medical management and periodic outcome evaluation, including treatment monitoring
  6) System evaluation and quality assurance
- The applicant institution(s) should have a Cystic Fibrosis Foundation-accredited Center or Affiliate program. The CF Center Director or Affiliate Director must provide a letter of support affirming that the applicant will be integrated into the CF Center. Each application should also engage the Director of the regional NBS Laboratory.
- Each application must describe the goals and framework for the project (including the NBS steps that need attention based on data presented in the application), the QI team and its structure, the designated leader and documentation of available time and commitment, a proposed timeline and meeting schedule that demonstrates the applicant's potential to complete the project in one to two years, and a willingness to share the findings/recommendations with all CF NBS programs and CF centers. Statewide QI proposals that engage the NBS lab and regional CF centers will be considered. Priority will be given to applications that address opportunities to achieve equity through CF NBS algorithm improvement and/or follow-up system enhancements. Examples of algorithm improvement include transformation from fixed to floating IRT cutoff values, expanded CFTR panels through incorporation of better molecular technologies such as next generation sequencing and improvements in state follow-up processes and programs. Efforts should be made, whenever possible, to incorporate the people served by NBS into the improvement work and identify "best practices."

V. Mentorship Requirements

Not applicable to this RFA

VI. Goals of Research Currently of Interest to CFF/Priority Areas

Not applicable to this RFA

VII. Review and Award

All applications are evaluated by a CFF established Screening Improvement Program review committee. Funding of awards is based on the priority score awarded to each application and the recommendations of the SIP Committee. Relevance of the proposed project to issues in CF is also considered in determining awards. All awards are subject to observance of the regulations and policies of CFF related to that category of support and are contingent upon the availability of CFF funds.

CFF may withdraw applications receiving low scores, and/or those deemed nonresponsive to the program announcement before the review meeting. In these cases, CFF will notify applicants if their application has been withdrawn without discussion.

VIII. Submission Information

Application Applications deadline: Monday, July 10, 2023 by 5:00 PM (Eastern)

Submit online through http://awards.cff.org
(Refer to Section X of these guidelines for specific submission instructions)

An application will be considered incomplete if it fails to comply with the instructions, or if the submitted material is insufficient to permit adequate review. CFF reviews applications electronically, and only documents submitted online at http://awards.cff.org will be reviewed.

General Timeline:

*Application Deadline	July 10, 2023
Committee Review	September 2023
Notification to Applicants	October 2023
Earliest Project Start Date	December 1, 2023

*We highly encourage all applicants pre-register their profile, institution, contacts, and title of their application at least two weeks prior to the application deadline. This will help to ensure the CFF Grants & Contracts Management and Administration (GCMA) Office is able to assist all applicant with any potential system-related queries prior to the Application Deadline.

IX. Letter of Intent Guidelines

Not applicable to this RFA

X. Full Application Guidelines

Applications must be submitted online at https://awards.cff.org

Documents should be typed using:

- Font: Times New Roman 12 or Arial 11
- Margins: No less than a half inch on each side

Note: *When all the documents have been uploaded to awards.cff.org, the system will compile them into a single PDF file. You may preview this file by selecting "Application Full Print", as well as exporting the compiled PDF file.*

To login, please visit: https://awards.cff.org

For all first-time applicants in the new Grants Management System, we ask that you pre-register to create a username and password for "http://awards.cff.org" and complete a profile prior to submitting an application. ***Please note:*** Applicants should register using the "Domestic Institution" or "International Institution" options to ensure that your profile aligns properly with the institution where the project will be conducted.

We also request that as you begin your application, you enter the title of your project, if available. If you are registered and cannot remember your password, click on the **"Forgot Password?"** link below the **"Login"** fields.

Once logged in, the award opportunities, including this Request for Applications (RFA), will be listed in the **Funding Opportunities** tab on the opening screen.

Locate the listing for the "**2023 Screening Improvement Program (SIP) Award for Optimizing the Diagnosis of Infants**" program. Click on the "Apply" button in the column on the far right to open the application form.

Applicants may stop at any point but must click the **"Save"** button at the bottom of each page *before exiting* in order to save their progress. When you wish to return to your draft application, please do not go through the "Funding Opportunities" tab. Instead, go to the "My Applications" tab in the right corner of the main page. When you are in the "My Applications" tab you will be able to find all your draft applications by clicking on the "Draft Applications" module.

The following sections are displayed as tabs across the application screen. Click on each section and follow the directions. Click "**Save**" as you complete each section.

Please note: Only select the "**Sign & Submit to AIO**" button after the application has been fully completed. This will trigger validation on all required fields and send the application to your Authorized Institutional Official "AIO" for review and signature through Adobe Sign.

GENERAL

Enter the title of your project, enter the project start and end dates, and complete any additional listed questions.

CONTACT PROFILE

If a profile was completed upon registration, the fields in this section will already be populated with the information entered in your Professional Profile. If you need to make any changes, you may update your profile in this section. Once updated you must "**Save and Validate**" prior to returning to continue your submission.

INSTITUTION

If a profile was completed upon registration, the applicant's/principal investigator's institution will be preloaded as the Lead Institution. Domestic applicants must verify their institution by entering the Employer Identification Number (EIN) or Tax Identification Number (TIN) to search the system for the correct institution. If the EIN/TIN is not located, you may add the legal institution. Please also confirm if the project site is the same as the legal institution.

Verification of Applicant Institution's Tax Status (upload as PDF documents):
The CFF GCMA Office must have a copy of the applicant institution's current W-9 and 501(c)3 letter, or other documentation verifying its Federal tax status and will not issue Award Letters to Awardees if these documents are not received and on file.

- Applicants from for-profit organizations must submit a copy of the applicant institution's W-9 and IRS documentation verifying the organization's Federal tax status. Awards are not issued prior to having these documents on file with the CFF GCMA Office.
- Non-U.S. applicants must provide a copy of the W-8BEN-E form (required). In addition, a tax equivalency letter should be uploaded, if available. If a tax equivalency letter is not available, applicants must upload a letter stating this documentation is not available.

International Applicants (if applicable):
Not applicable to this RFA

CONTACTS

Please note: The INSTITUTION tab must be completed prior to adding internal contacts to ensure that the contacts are properly associated with the applicant institution.

Complete the required contact fields by searching by name for existing contacts at your institution for each role. If the desired institutional contact is not available in the system, you may select "**Add Internal Contact**" to create a basic contact profile in order to add the individual to your application.

Additional contacts not associated with the applicant institution may also be added. These contacts are considered additional contributors involved in the proposed research plan. These may include consultants, collaborators, or subcontractors. In order to add contacts external to the applicant institution, please select the appropriate "Add Subcontractors" or "Add Consultants/Collaborators" button(s) and add the contacts in the table, then click "Save".

ABSTRACTS/RELEVANCE

In the space provided online for abstracts, provide a statement of no more than 2,000 characters (including spaces) explaining the subject of the research proposal and its relationship to CF. Two different abstracts are required, as follows:

- **Lay Abstract**: This statement will be used to inform the non-scientific departments of CFF and the general public of the nature of this work. Applicants should not include any confidential or proprietary information, including intellectual property, in the lay abstract.
- **Scientific Abstract**: This statement will be used to inform the scientific community.
- **Summary of Relevance to CFF mission**: All applications are reviewed and scored not only on scientific merit but also on relevance to CFF's mission:

  The mission of the Cystic Fibrosis Foundation is to cure cystic fibrosis and to provide all people with CF the opportunity to lead long, fulfilling lives by funding research and drug development, partnering with the CF community, and advancing high-quality, specialized care.

  Provide a statement of no more than 3,000 characters (including spaces) summarizing the relevance of the proposed research to the health and well-being of CF patients, for a scientific audience who may or may not have a background in the subspecialty of the proposed research.

BUDGET

Select the "**Edit Budget**" button under Application Budget, to enter and begin completion of the application's budget detail for each year of funding being requested. Awards funded through this RFA are not to exceed $75,000 per year (plus up to 12% of indirect costs) for two (2) years.

The following budget categories are offered under this program:

Salaries & Benefits - List the names and positions of all professional and non-professional personnel involved in the project, whether or not salaries are requested. Indicate the percent effort on the project for all personnel. In accordance with National Institutes of Health (NIH) policy, salary requests may not use an institutional base salary in excess of the current federal salary cap of **$212,100**. Fringe benefits may be requested if they are treated consistently by the applicant institution as a direct cost to all funding agencies and foundations.

Consultant Costs - Give the name and institutional affiliation of any consultant who has agreed to serve in this capacity, including statisticians and physicians in connection with the project if they are not listed under personnel. In the budget justification, briefly describe services to be performed, the number of days, rate of compensation, per diem and any other associated costs. Qualifying consultants are individuals that are generally not employed at the applicant institution and/or are consulting independently to the project.

Travel - Describe the purpose of any CF-relevant travel. Please note: expenses for travel outside the North American Continent, including travel to Hawaii, Puerto Rico, and other U.S. territories are not allowable expenses without prior written approval from the CFF GCMA Office. **Travel expenses may not exceed $2,000 per person per year**. Registration fees associated with conferences are in addition to this allowance should be listed under "Other Expenses".

Consumable Supplies - Itemize supplies e.g. glassware, chemicals, animals, in separate categories and give the estimated cost of each category. If animals are involved, state the number, unit purchase cost, and unit care cost.

Major Equipment - List all items of equipment greater than **$5,000** requested and the cost of each item. If funds are requested to purchase equipment that is equivalent to items listed under "Facilities Available", justify the duplication. Justify any item of equipment for which the need may not be obvious.

Other Expenses - Itemize other expenses by major categories, such as duplication costs, publication costs, minor equipment (under $5,000), computer charges, conference registration fees, etc. Tuition costs may not be requested.

Patient Research Costs – Funds may be requested for patient research costs specifically related to the proposed QI project. The basis for estimating funds requested in this category must be justified and applicants must provide detailed information regarding the proposed costs (e.g., number of procedures, cost per procedure, ancillary costs). The scientific need for patient research costs will be considered in the review. Negotiation of these costs are between the applicant institution and the service provider.

Subcontractors Summary – If applicable, detailed budgets and budget justifications for each subcontract, including indirects, must be provided for each year of support. Subcontractors are added in the prior section entitled **CONTACTS**. The lead/prime applicant (PI) and/or Grants Officer can initiate/complete the subcontract budget. After adding Subcontractor(s), in order to access the subcontract budget activity, please select the "**BUDGET**" tab of the application and click the "**Open**" button next to each listed subcontractor. After completing the subcontract budget activity, please select "**Pending PI Acceptance**", as well as "**Submit**" to ensure the subcontractor budget is included as part of the main application budget.

For applications that include a subcontract with a third party, the applicant may request indirect costs on the first $25,000 of each subcontract per project period. Negotiations of subcontracts are between the applicant institution and the subcontractor.

Budget Detail – Indirect Costs

Indirect costs of up to twelve percent (12%) may be requested from CFF. Indirect costs may be requested for all expenses except for the following:

- Major equipment (items over $5,000 in value)
- Computer software
- Software licenses

FULL APPLICATION UPLOADS

Download the available templates applicable to the project, upload the completed templates, as well as the additional application components as outlined below. All documents must be uploaded in PDF format to the corresponding attachment types within this section. Templates available for download include:

- Budget Justification
- Project Plan
- Collaboration Detail (required for multi-site studies, if applicable)
- Biographical Sketches of Key Personnel
- Other Support (NIH format)
- Facilities Available

BUDGET JUSTIFICATION (template available for download)

Describe costs listed in the Budget Detail. Use major categories, such as Salary & Benefits, Consumable Supplies, etc. Justify all items and make sure amounts and figures listed in the narrative are consistent with those listed in the Budget Detail(s).

PROJECT PLAN – Quality Improvement Plan (template available for download)

- Key figures and legends must be included in the QI Project Plan. If uploaded as Appendices, they will NOT be reviewed.
- Type the PI's name in the space available in the header of the template. The template will track page numbers at the bottom.
- Page limit: Twelve (12) single-sided pages, not including the Literature Cited. Applications exceeding this page limit will not be reviewed. Include sufficient information to permit effective review without reference to previous applications. Information should be presented in a clear and concise manner, while being specific and informative.
- If your application is a resubmission of an earlier application, revisions should be clearly indicated by a change in font, bolded or underlined. CFF will not review resubmissions that have not been revised.
    a. **Hypothesis and Specific Aims:** State concisely and realistically the intent of the proposed QI project and the hypothesis to be tested. The specific aims should be relevant to the mission of the Cystic Fibrosis Foundation. Do not exceed one page.
    b. **Background and Significance**: Briefly describe the background. Critically evaluate existing knowledge and specifically identify the gaps that the project is intended to fill. Concisely state the importance and rationale of this QI project by relating the specific aims to longer-term objectives. This section should also show the potential importance of the proposed work to CF in particular those listed as areas of special interest to CFF. In addition, describe the relationship of the proposed work to your long-term career goals. Preference will be given to applicants who express an interest in a long-term career in CF-related work and research. Do not exceed three pages.

c. **Preliminary Results**: If applicable, provide a detailed discussion of any preliminary results.
d. **Quality Improvement Project Design and Methods**: Provide a detailed discussion of the QI project design and procedures to be used to accomplish specific aims. Please discuss: study hypothesis; primary and secondary outcome measures; study design; details of the intervention, timeline, a description of your proposed data analysis and statistical procedures. Although no page limit is specified for this section, make every attempt to be concise and succinct. Discuss the potential limitations as appropriate and alternative strategies for achieving the aims.
e. **Consultant Arrangements**: If the proposed project includes consultant arrangements and/or collaboration with other individuals outside the applicant's group, describe the working relationships and support this description by letter(s) of intent signed by collaborating individual(s). If clinical material required by this project is to be furnished by other individuals, include a statement from these individuals agreeing to their participation and precautions taken to ensure anonymity of patients.
f. **Literature Cited**: References should be numbered in the sequence that they appear in the text and listed at the end of the QI Project Plan. Each citation must include the names of authors, the name of the journal or book, volume number, page number and year of publication (titles are optional).

COLLABORATION DETAIL (template available for download, if applicable)
For multi-site studies only: On the provided template please list each collaborator, including their institute and responsibilities or resources they are dedicating to the project.

BIOGRAPHICAL SKETCHES OF KEY PERSONNEL (template available for download)
Complete and upload an NIH Biographical Sketch for all key project personnel, beginning with the Applicant/Principal Investigator. International applicants can upload a biosketch that is equivalent in content to the NIH template provided. (CFF defines “key personnel” as any individual with an advanced degree that will play an instrumental role in the accomplishment of the research project.) Do not exceed five (5) pages per person.

OTHER SUPPORT (template available for download)
Complete and upload the Other Support form for all key project personnel, beginning with the Applicant/Principal Investigator. There is no page limitation. Information on other support assists CFF in the identification and resolution of potential sources of overlap. Scientific and budgetary overlap should be minimized. Commitment of an individual’s effort greater than 100 percent, is not permitted.

FACILITIES AVAILABLE (template available for download)
Describe the facilities and equipment available at the applicant’s institution that will be used for this project, such as laboratory, clinical, animal, computer, office, etc. Provide any additional information about the environment, including any support services available that will be utilized. Describe their pertinent capabilities, proximity and anticipated extent of use. If facilities or equipment at a consultant’s or collaborative site will be used, they should be identified and clearly described. There is no page limit. Use continuation pages, if necessary.

APPENDICES (upload as PDF documents, if applicable)
Appendices are restricted to the following three (3) categories:
- Up to three (3) reprints of the applicant’s work relating to the general area of work in the proposal.
- Signed Letters of Support, collaboration and/or reference:
  - If the applicant is not a CF Center Director or Co-Director, a letter of support from the Center Director is required.
  - If there are Co-Investigators, a letter of collaboration is required from each.
  - Letters of reference are optional but encouraged.

- If applicable, certification of IRB approval, or other applicable organization assurances documents such as IACUC and IBC Approval Letters, if available at the time of application.

**No other types of appendices will be reviewed.*

***Organization Assurances & Certifications**

CFF requires, as applicable, that all U.S.-based awardees obtain Institutional Review Board (IRB) approvals for human subject research, Institutional Biosafety Committee (IBC) approval for recombinant or synthetic nucleic acid research, and Institutional Animal Care and Use Committee (IACUC) approval for animal research, (see additional information regarding these approvals below). Copies of these approvals, if available at the time the application is submitted, must be uploaded with the application as appendices. CFF will not release payments to awardee institutions until these documents are received and on file with the CFF GCMA Office.

Awardees based outside of the U.S. must comply with the applicable equivalent regulations in their respective countries and provide copies of approvals as soon as they are available. CFF will not release payments until these documents are received and on file with the CFF GCMA Office.

Research Involving Human Subjects: CFF policy pertaining to the protection of individuals as research subjects requires that for each proposal awarded, the awardee institution certify in writing that an Institutional Review Board (IRB) has reviewed and approved the procedures for the use of human subjects, or human organs, tissues and body fluids, in the proposed research, in accordance with the Department of Health and Human Services policies found at https://www.hhs.gov/ohrp/regulations-and-policy/index.html. In the event the IRB has determined a study is exempt, documentation demonstrating the exempt status must also be submitted to the CFF GCMA Office.

Research Involving Recombinant or Synthetic Nucleic Acid Molecules: All research involving recombinant or synthetic nucleic acid and human gene transfer studies supported by CFF must meet the requirements contained in the document *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (updated April 2019*). This publication and announcements of modifications and changes to the NIH Guidelines are available from the Office of Science and Policy, National Institutes of Health, 6705 Rockledge Drive, Ste 750, MSC 7985, Bethesda, MD, 20892-7985 or online at https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf.

Research Involving Animals: Applications submitted to CFF involving the use of animals must meet the guidelines of the National Institutes of Health found at https://grants.nih.gov/grants/olaw/olaw.htm, which require that all proposed studies be reviewed and approved by an Institutional Animal Care and Use Committee (IACUC). In addition, CFF awardee institutions and laboratories must be accredited by the American Association for Accreditation of Laboratory Animal Care (AAALAC) and/or have other verifiable assurances that the institution and laboratory meet appropriate standards.

Validation and Submission

Prior to selecting "**Sign & Submit to AIO**", please complete a thorough review of the entire application. The "**Sign & Submit to AIO**" button will trigger validation on all required fields and identify any upload errors or incomplete fields. Upon selecting Sign & Submit to AIO, the ability to edit the application will be locked pending review and approval by your AIO.

After selecting **Sign & Submit to AIO**, the applicant will receive an email asking them to sign the application Face Page electronically using Adobe Sign. Once signed by the PI, the Face Page will then be routed to the AIO contact that is listed on the application for review and signature.

To ensure the application is fully signed and submitted ahead of the Application Deadline for this program, please be sure to complete the application, and begin the Sign & Submit to AIO process in advance of the 5:00 PM EST deadline. The status of your application will display "Submitted" once fully signed, to indicate that your application has been received by CFF.

XI. Other Information

Not applicable to this RFA

XII. Contact Information

For technical support and program/content information:
Primary CFF GCMA Office contact nappleton@cff.org or 301-841-2614

For scientific questions:
Albert Faro, M.D. afaro@cff.org