Clinical Research Award Plus (CRA+) Concept Proposal & Planning Grant

2020 Funding Cycle

POLICIES AND GUIDELINES

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Application Deadline: February 10, 2019

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Grants and Contracts Office ♦ (301) 841-2614 ♦ grants@cff.org

I. ABOUT THE CYSTIC FIBROSIS FOUNDATION

The mission of the Cystic Fibrosis Foundation (CFF) is to cure cystic fibrosis (CF) and to provide all people with the disease the opportunity to lead full, productive lives by funding research and drug development, promoting individualized treatment, and ensuring access to high-quality, specialized care.

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

II. CF FOUNDATION RESOURCES FOR RESEARCHERS

The Cystic Fibrosis Foundation supports the development of a number of helpful tools and resources to assist the research community in accelerating the progress toward new scientific knowledge of and new therapies for cystic fibrosis. For more information on Tools and Resources for the CFF research community, please visit: https://www.cff.org/Research/Researcher-Resources/Tools-and-Resources/

CFF Patient Registry Data

The CF Foundation Patient Registry (CFFPR) collects information on the health status of people with cystic fibrosis who receive care in CF Foundation-accredited care centers and agree to participate in the registry. This information is used to create CF care guidelines, assist care teams providing care to individuals with CF, and guide quality improvement initiatives at CF centers. Researchers also use the registry to study CF treatments and outcomes and to design CF clinical trials.

The CFFPR is an invaluable tool for researchers who are interested in conducting studies about people with CF in the United States. About 50,000 individuals have been followed in the Registry, and many have been included for over 20 years. In addition, we recently linked the CF Foundation Patient Registry with the Pediatric Health Information System (PHIS) database. Investigators at PHIS sites can request to use these linked data. Instructions on how to request CFFPR data for your research project is included in the application instructions below:
CFF Patient Registry Data Request Application

CFF Biorepository

Cystic fibrosis biological samples are available to qualified researchers to help develop promising new studies that will support CF research and aid in drug development and drug discovery. Biorepository samples come in many different forms: blood, urine, stool, tissue, and other material. These samples are stored under appropriate conditions that ensure they are preserved for future analysis.

Since 2006, the Cystic Fibrosis Foundation has collected and stored samples from a variety of clinical trials. The CF Foundation has developed a database that combines information from these samples with data from CF clinical trials and the CF Foundation Patient Registry to create a unique and specific sample profile. Instructions on how to request CFF Biorepository samples for your research project is included in the application instructions below:

https://www.cff.org/Research/Researcher-Resources/Tools-and-Resources/CFFT-Biorepository/

Community Voice

The CF Foundation is committed to ensuring that the CF community's voice is heard in all of our activities. In December 2014, the CF Foundation created Community Voice, formerly known as the CF Adult and Family Advisors group, to serve as a consultative body and partner to the Foundation on various activities. Research Voice, a sub-committee within Community Voice, consists of people with CF and their family members who undergo special training on the basics of clinical research to provide insight and feedback to the research community.

Opportunities to partner with the community occur throughout the stages of a research project. Recently, several CFF funded investigator-initiated clinical research projects have utilized community engagement through Community Voice to successfully execute and complete their projects. The CF Foundation strongly encourages you to engage people with cystic fibrosis throughout the stages of clinical research. Based on your goals and objectives, the CF Foundation will work with you to determine which mechanisms are most appropriate. To learn more about how community insights can help you optimize your research project, email **CommunityVoice@cff.org**.

CFF Therapeutic Development Network Coordinating Center (TDN-CC) Collaboration:

CRA+ proposals may request the use of Therapeutics Development Network (TDN) resources or assistance in identifying potential collaborators in order to successfully execute a large, multi-center clinical study. Letters of Intent requesting the use of TDN resources will undergo additional review to evaluate the capacity of the TDN to provide any requested resources. To learn more about TDN resources, please visit: https://www.cff.org/Research/Researcher-Resources/Therapeutics-Development-Network/

National Resource Centers

Specialized procedures are often needed to measure the outcomes of cystic fibrosis clinical trials. These include both laboratory-based measurements, such as cytology and inflammatory markers, and interpretive outcomes, such as computed tomography and nasal potential difference. NRC provide centralized expertise for a variety of CF research outcome measures. For more information about National Resource Centers, please visit: https://www.cff.org/Research/Researcher-Resources/Therapeutics-Development-Network/Working-with-the-TDN/National-Resource-Centers/

III. PROGRAM DESCRIPTION

Investigator-Initiated Research Programs

The Foundation's Investigator-initiated Clinical Research Programs aim to provide support for academic clinical research projects that have the potential to make an important contribution to the CF Foundation's mission. Academic clinical research projects may address diagnosis, treatment, management of disease or symptoms, or the pathophysiology of CF using clinical (observational or interventional), translational or epidemiologic study approaches.

The CF Foundation funds investigator-initiated clinical research through the Clinical Pilot and Feasibility Award (CP&FA), Clinical Research Award (CRA), the new Clinical Research Award Plus (CRA+), and other various targeted funding opportunities that occur throughout the year.

Funding for any investigator-initiated clinical research award is a tier two process. The CF Foundation requires CP&FA, CRA, and CRA+ applicants to submit either a Letter of Intent (LOI) or Concept Proposal in advance of a full application. Full applications are accepted on an invite-only basis.

In 2018, the CF Foundation received 79 LOIs for the CP&FA and CRA. The Foundation invited 40 investigators to submit full applications. Of those received, the Foundation funded 10 CP&FA and nine CRAs. The breakdown for 2018 funding is shown below.

2018	Clinical Pilot & Feasibility Award		Clinical Research Award	
	Spring 2018	Fall 2018	Spring 2018	Fall 2018
LOIs Received	17	22	17	23
Full Applications Received	9	9	11	11
Funded	6	4	3	6

Table 1: Number of LOIs and full applications received and funded for the 2018 Spring and Fall CP&FA and CRA cycles.

Areas of Interest

The CF Foundation seeks applications for the Clinical Research Award from all areas of clinical research that will have an impact on the lives of people with CF. However, the following research areas are of particular interest to the CF Foundation as they will address critical needs of people with CF:

- Studies that investigate CF disease complications (lung, GI tract, liver, pancreas, reproduction, mental health, endocrine etc.)
- Strategies to improve care and quality of life of people with CF
- Assessment and validation of biomarkers, clinical trial tools, outcome measures and efficacy endpoints
- Translational or clinical studies in lung transplant[1] research
- Characterization of CF disease manifestations and management in the era of highly effective modulator therapy
- Novel interventions that improve CF patient care and outcomes
- Studies designed to translate laboratory findings of disease pathogenesis/treatment to clinical evaluation

[1] In 2017, the CF Foundation created the Lung Transplant Initiative to address the unmet needs of people living with cystic fibrosis with advanced lung disease. The mission of this initiative is to improve the care and long-term outcomes of individuals with CF and advanced lung disease. For more information about this initiative, or the CF Foundation's research priorities in lung transplant research, please email Al Faro (afaro@cff.org).

Areas of Encouragement

In addition to CF Foundation Areas of Interest, extensive survey input from the CF community (people with CF, family members and caregivers) have identified key research Areas of Encouragement that are most important to them. The areas selected by the CF community are listed below in order of prioritization. Applications may address any topic area advancing CF care, treatment, or research. However, applications addressing the following areas in CF are particularly encouraged:

- Respiratory Microorganism Detection and Treatment
- Gastrointestinal symptoms (including, but not limited to, GERD, DIOS, and Pancreatitis)
- Reducing Treatment Burden
- CF-related Diabetes
- Diet and Nutrition
- Mental Health
- CF-related Liver Disease (including cirrhosis and non-cirrhosis, gall stones, hepatic steatosis, and other clinical manifestations of portal hypertension)
- Exercise
- Sinus Disease
- Allergies and Asthma
- Alternative/Holistic Treatments and Therapies
- Sexual Reproductive Health
- Bone/Joint Heath
- Pain Management

IV. CLINICAL RESERCH AWARD PLUS OVERVIEW

The intent of the Clinical Research Award Plus (CRA+) is to support large, multi-center, investigator-initiated clinical research studies that require a higher funding level and longer periods of time, than offered through the Clinical Research Award (CRA) funding mechanism. Given their size, the number of CRA+ awards will be limited. CRA+ proposals must have the potential to make an important contribution to the CF Foundation's mission, and should address diagnosis, treatment, management of disease or symptom, or the pathophysiology of CF. Proposals can be either an interventional trial, observational study, or support for research working groups/collaborations.

Recipients of the Concept Proposal Planning Grant (see below) or those invited to submit full applications are required to participate in an ongoing, constructive dialogue with CFF prior to submitting a full application.

Concept Proposal Planning Grant

The purpose of the Concept Proposal is to provide the CF Foundation with sufficient detail to determine if the proposal addresses a CF Foundation priority research area and to determine if the application is appropriate for the CRA+ funding mechanism. Concept Proposals may include requests for planning support to develop a full application, the use of CFF Therapeutics Development Network (TDN) resources, and/or assistance in identifying potential collaborators in order to successfully execute a large, multi-center clinical study. Concept proposals requesting TDN collaboration will undergo additional review to evaluate the capacity of the TDN to provide any

requested resources. The Policy and Guidelines for the CRA+ full application is available only to those who have an accepted concept proposal. The Policy and Guidelines for the CRA+ full application are not found in this document.

General Guidelines:

- Applicants may request funding for a Planning Grant of up to $75,000, plus twelve (12) percent indirect costs.
- Planning Grants may be approved for up to a one (1) year period

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 independent investigators.
  - Must be a M.D., D.O., Ph.D. or dual M.D./D.O., Ph.D.
  - To bring new technologies and expertise to the CF field, investigators without experience in CF research are encouraged to apply
- Industry-sponsored research projects are not eligible to apply through this program and instead should consider applying to the Therapeutics Development Awards program. For additional information, please contact grants@cff.org.

V. CONCEPT PROPOSAL PLANNING GRANT REVIEW AND AWARD

Concept Proposals considered appropriate for the CRA+ mechanism will be reviewed by the Clinical Research Award Plus Committee and CFF. Concepts Proposals that don't fully meet the intent of the CRA+ award may be re-directed to other CFF funding mechanisms. The CRA+ Committee will evaluate Concept Proposals on their scientific merit and CF mission relevance.

Projects requesting the use of the Therapeutic Development Network resources must undergo further review by the CFF, the TDN Protocol Review Committee (PRC), and the Clinical Research Executive Committee (CREC) prior to full application submission. Instructions for submissions to the PRC will be provided by the TDN upon approval of the Concept Proposal. Considering that CRA+ projects are sizable, an increased level of monitoring by CFF should be anticipated.

Planning Grant awards are made based upon the availability of funds, the scientific merit of the application, likelihood of success, and the relevance to CFF's mission.

Awards are also approved by the CFF Board of Directors based on the priority score assigned to each application and recommendations of the CRC and CFF Program Officers. All awards are subject to compliance with applicable regulations and CFF policies.

Chief reasons for assigning low priority scores to applications during review include the following:

- Insufficient information or documentation
- Inadequate statement of hypothesis, experimental design or methods

- Failure of the applicant to describe potential relevance of the proposed study to issues in CF
- Failure of the applicant to document the necessary skills or training to accomplish the goals of the proposal
- Failure of the applicant to meet all the criteria described in these guidelines
- Failure of the applicant to demonstrate likelihood of success

CFF may withdraw Concept Proposals deemed not appropriate for the CRA+ funding mechanism. In these cases, CFF will notify applicants if their application has been withdrawn and may recommend application to a different CFF funding mechanism.

VI. SUBMISSION INFORMATION & GENERAL TIMELINE

Applicants may only submit one (1) application per funding cycle.

Submit online submission at proposalCENTRAL: http://proposalcentral.com/
(Refer to Section VII of these guidelines for specific submission instructions.)

General Timeline:

Concept Proposal Deadline _____February 10, 2020
Review by Ad hoc Committee _____mid-April 2020
Notification to Applicants _____May 2020
Earliest Start Date for Planning Grants _____July 1, 2020

VII. APPLICATIONS GUIDELINES

Application Deadline: February 10, 2020 at 5:00 PM (EST)

Applications must be submitted online at proposalCENTRAL: https://proposalcentral.com/

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 proposalCENTRAL will be reviewed.

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 proposalCENTRAL, the system will compile them into a single PDF file in the correct sequence as shown in Section VIII. ELECTRONIC APPLICATION CHECKLIST.

Log-in at proposalCENTRAL: https://proposalcentral.com/

First-time applicants must register to create a user name and password for proposalCENTRAL and will need to complete a profile online before applying. If you are already registered and cannot remember your password, click on the **"Forgot Your Username/Password?"** link below the **"Application Login"** fields. ***Note****: Use the Customer Service link on the top right of each screen as needed.*

Grant and award opportunities, including this, are listed on the opening screen, but you must be logged in first to see them.

Select the gray tab labeled **"Grant Opportunities"** found in the upper right-hand side of the page.

Click on the light blue **"Filter by Grant Maker"** button to the left and scroll down to locate **Cystic Fibrosis Foundation in** the list.

Locate the listing for the **"CRA+ Concept Proposal and Planning Grant"** program. Click on the **"Apply Now"** 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 before exiting in order to save their work. When logging in to continue, click on the blue tab, **"Proposals**," and then the **"Edit"** button.

The following sections are listed in the navigation menu to the left of the application screen. Click on each section and follow the directions.

1. **Title Page:** Enter the title of your project and indicate whether you are requesting support for a planning period.

2. **Download Templates & Instructions:** Download the available templates applicable to the project, fill them out and upload them when completed in Section #8. Templates available include:
   - Concept Proposal
   - Budget Detail
   - Budget Justification
   - Budget Summary for future Full Application
   - Planning Period Statement of Work (SOW)
   - Biographical Sketch(es) of Key Personnel
   - Other Support (NIH format)

3. **Enable Other User to Access this Proposal:** Complete this section online if you wish to designate access to another individual, such as an assistant who has registered on proposalCENTRAL. Enter the email address of the individual and in the **"Permissions"** column, use the pulldown menu to select the type of access you wish to give. Please note that only

delegates who are granted **"Administrator"** rights can submit applications on behalf of the applicant. Check the **"Auto Notify"** box and then **"Save"**.

4. **Applicant/PI:** 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, click the **"Edit Professional Profile"** button and follow the instructions. If a profile was not completed, enter the required information and click **"Save"**.

5. **Institution & Contacts:** If a profile was completed upon registration, the Principal Investigator's (PI) institution will be preloaded as the Lead Institution. If a profile was not completed, enter the required information and click **"Save"**. Be sure to use the full legal name of the institution.

6. **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 mission.

     The mission of the Cystic Fibrosis Foundation is to cure cystic fibrosis and to provide all people with the disease the opportunity to lead full, productive lives by funding research and drug development, promoting individualized treatment, and ensuring access to high-quality, specialized care.

     Provide a statement of no more than to 3,000 characters (including spaces) summarizing how the proposed research addresses one or more of identified research priorities for a non-scientific audience who may or may not have a background in the subspecialty of the proposed research (see Section III of these guidelines). Describe how your project will impact the CFF mission. Describe how you will engage the CF Community in your research.

7. **Budget Summary:** Fill in the start and end date and applicable amounts for each year of support requested by completing the online fields (Period 1). Funding of up to $75,000 for one-year may be requested. Allowable costs are described below in section 8.B. *Note: A separate Budget Detail template and Budget Justification template downloaded in Section #2 must be completed and uploaded in Section #8 in proposalCENTRAL for each year of the award. The amounts included in this uploaded Budget Detail must match the amounts entered here in the Budget Summary online.*

8. **Concept Proposal & Supporting Documents:** In this section, upload the completed templates downloaded in Section #2 above. Fill out the fields describing the attachment, select the

attachment type from the pulldown menu, choose the file to be uploaded, and click the **"Upload Attachment"** button to upload the file. Do this for each attachment.

Below are instructions specific to each template as well as additional information regarding other application components.

A. Concept Proposal (template available for download)

Upload a PDF copy of the completed document. Maximum of seven (7) pages (not including the literature cited). At the top of each page, type the PI's name. Each page must be sequentially numbered at the bottom. Components should include:

- **General Questions:** Please respond to the following questions below:
  - **a.** Do you plan on applying for joint funding with another funding agency? If so, please describe the other funding opportunity and the general timeline of review.
  - **b.** Does your project utilize a study population that builds on a current project or clinical study? If so, please describe any time sensitive aspects related to study population enrollment or ancillary study feasibility.

- **Project Description:** The plan should be clear, concise, specific and informative. The aspects described below should be covered in your Statement of Work.
  - **a. Background, Rationale, and Significance:** Briefly describe the background and rationale for the proposed study concept. Critically evaluate existing knowledge and specifically identify the gaps that the project is intended to fill. Concisely state the importance and rationale of this research by relating the specific aims to longer-term objectives. This section should also show the potential importance of the proposed work to CF.
  - **b. Preliminary Studies**: Summarize any preliminary work pertinent to this application that has been undertaken by the Principal Investigator(s) and/or information that will establish the competence and/or experience of the investigator(s) to pursue the proposed study. Titles, complete references and supplemental charts, graphs, etc., may be submitted in the Appendix (see Section H).
  - **c. Study design concept:** Briefly describe the study design concept and the research idea. Specify the purpose of the proposed research, the research question(s), and research hypothesis. Feasibility assessment for subject recruitment should also be included. Please include a brief statistical analysis section highlighting key endpoints and a preliminary power or sample size justification for scope and size of study proposed.
  - **d. Study Design and Planning:** State whether assistance from the CF Foundation or the TDNCC is being requested to help design and plan your study. If the use of the TDNCC is requested for study design and planning, the TDNCC will scientifically collaborate to develop a study proposal ready for scientific review for the TDN.
  - **e. Coordinating Center and Operational Plan.** State whether you are seeking resources from the TDNCC to execute the proposed study. If you are working with a coordinating center other than the TDNCC, briefly describe their responsibilities and operational capacities for supporting the study.

f. **Literature Cited:** References should be numbered in the sequence that they appear in the text and listed at the end of the Concept Proposal. 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).

B. Budget Detail and Justification - Planning Grant (separate templates available for download)
Fill out the Budget Detail and Budget Justification templates for the one-year Planning Grant. In the space provided on each page, indicate the year or period as well as start and end dates for the proposed budget period.

Be sure the Budget Detail matches the online budget summary in Section #7.

Budget Detail – Direct Costs

Salary & 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. For each individual, be sure to complete all fields on the Budget Detail in full on the template provided. 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 $192,300 when calculating salary requests, the NIH cap must be adhered to. 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.

Subcontractors – Detailed budgets for each subcontract, including indirects, must be provided for each year of support (complete and upload a Budget Detail and Budget Justification template for each subcontract). 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.

Travel – Describe the purpose of any CF-relevant travel. Please note: expenses for travel outside the North American continent for domestic applicants, including travel to Hawaii, Puerto Rico, and other U.S. territories are not allowable expenses without prior written approval from the Grants and Contracts Office. Travel can be used by study personnel to attend appropriate meetings (e.g.: NACFC, TDN Spring meeting) and/or site visits for monitoring and/or quality assurance.

Registration fees associated with conferences should be listed under "Other Expenses."

Other Expenses – Itemize other expenses by major categories, duplication costs, publication costs, conference registration fees, computer charges, and other research costs etc. Justify all items.

Budget Detail – Indirect Costs

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

- Computer software
- Software licenses

Budget Justification

Describe costs listed in the Budget Detail. Use major categories, such as Salary & Benefits, Consultant Costs, Equipment, etc.

C. Budget Summary for future Full Application (template available for download)

Please provide a budget summary estimate for the future full study (post-Planning Grant). Summary by category only, detail not required.

D. Planning Period Statement of Work (template available for download)

Provide details on the tasks that will be performed during the planning period. Include details on who will be responsible to complete the task and the general timeline to complete each task.

E. Biographical Sketch(es) of Key Personnel (template available for download)

Complete and upload an NIH Biographical Sketch for all key project personnel, beginning with the Principal Investigator. (CFF defines "key project 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.

F. Other Support (template available for download)

Complete and upload an "Other Support" form, for all key project personnel, beginning with the Principal Investigator. There is no page limitation.

G. Verification of Applicant Institution's Tax Status (upload separately as PDF documents)

The Grants and Contracts 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 Form 147C, or other documentation verifying the organization's Federal tax status. Awards are not issued prior to having these documents on file with the Grants and Contracts Office.

H. Appendices (upload as PDF documents)

Appendices are restricted to the following two (2) categories:

- Up to three (3) reprints of the applicant's work relating to the general area of research in the proposal may be uploaded in PDF format.

- Signed Letters of Collaboration
  - If there are Co-Investigators, a letter of collaboration is required from each.

9. **PI Data Sheet:** Fill in the required fields, save and exit.

10. **Print Face Pages:** Follow the prompts on the screen to generate and print a Face Page. The Face Page will be populated automatically with data entered in the online application (applicant's name, institution, title of application, etc.). The Face Page must be signed by the Principal Investigator and Authorized Institutional Official and uploaded in Section #8. Co-Principal Investigators, if any, are not expected to sign the Face Page.

11. **Validate:** Upon completing your application, click on the **"Validate"** button on the main screen. Attend to any omissions/errors as prompted onscreen, and then click **"Validate"** again.

12. **Submit:** Click on the gray button with blue lettering. 

CFF will not receive your application until and unless the **"Submit"** button is clicked.

    Confirmation: Applicants will receive an e-mail confirmation from proposalCENTRAL (not from CFF) that the application was successfully submitted. This e-mail will be your only acknowledgement. If you do not receive this confirmation, please contact proposalCENTRAL immediately to ensure that your submission was submitted and processed.

For technical support with the online application:

proposalCENTRAL at pcsupport@altum.com or

800-875-2562 on weekdays, 8:00 a.m. to 5:00 p.m. (Eastern)

For program/content information:

CFF Grants and Contracts at grants@cff.org or 301-841-2614

VIII. ELECTRONIC APPLICATION CHECKLIST

Application Deadline: February 10, 2020 at 5:00 PM (EST)

Applications must be submitted at proposalCENTRAL: https://proposalcentral.com/

The complete application must be submitted online, and no other documents will be reviewed.

Face Page (upload) which includes:

- ☐ Signatures
  - ☐ Principal Investigator/Applicant (PI)
  - ☐ The Official authorized to sign on behalf of the Awardee Institution
- ☐ Applicant/PI information (online)
- ☐ Complete Institution and PI Contact Information, including correct mailing address (online)

Concept Proposal & Supporting Documents

- ☐ Abstracts – Summary of Relevance (online)
- ☐ Concept Proposal (upload)
- ☐ Budget Detail (upload)
- ☐ Budget Justification (upload)
- ☐ Budget Summary for future Full Application (upload)
- ☐ Planning Period Statement of Work (SOW) (upload)
- ☐ Biographical Sketch(es) of Key Personnel (upload)
- ☐ Other Support (NIH format) (upload)
- ☐ Verification of Applicant Institution's Tax Status (upload)
  - ☐ W-9 (U.S. applicants)
  - ☐ Federal (IRS) tax status letter or equivalent tax status letter
- ☐ Appendices (upload as PDF documents, if applicable)
  - ☐ Up to three (3) reprints of the applicant's work relating to the general area of research in the proposal
  - ☐ Signed Letters of Collaboration
- ☐ Signed Face Page