

The mission of the Cystic Fibrosis Foundation (CFF) is to assure the development of the means to cure and control cystic fibrosis (CF) and to improve the quality of life for those with the disease. To meet this mission, various types of grants are offered to support meritorious research ranging from basic laboratory investigation to clinical management of CF. For all awards, proposals that involve collaboration between an approved CFF Care Center and an institution with basic and/or clinical research are encouraged.

**HARRY SHWACHMAN CYSTIC FIBROSIS CLINICAL INVESTIGATOR AWARD
POLICIES AND GUIDELINES**

The Harry Shwachman CF Clinical Investigator Award provides the opportunity for promising, clinically trained physicians with a commitment to research to develop into independent biomedical researchers who have active involvement in CF-related areas. The award helps facilitate the transition from postdoctoral training to an academic career as an independent investigator. The award enables candidates to undertake three years of research, which is tailored to the individual's interests and needs, with a sponsor(s) competent to provide appropriate research guidance and supervision.

This award provides support for three years at a level of up to \$91,000 in direct costs annually (no indirect costs provided). All funds must be used to support the original awardee. Support is based on a full-time, twelve-month appointment. Budget guidelines and restrictions follow:

- Salary support of up to \$76,000 per year may be requested;
- Supplementation of salary from other sources is allowable;
- A minimum of 70% of the applicant's time must be devoted to research;
- Up to \$15,000 per year may be requested for supplies, travel, minor equipment, etc.;
- Purchase of major equipment (≥ \$5,000) not allowable;
- **U.S. citizenship or permanent resident status is required.**

SUBMISSION INFORMATION

Application Deadline: First Wednesday of September at 5:00pm (Eastern Time)

Applications must be submitted at Proposal Central: <https://proposalcentral.altum.com/>. The signed, original Face Page should be returned to CFF and **postmarked** by the same date. Late applications will not be accepted and the deadline will not be waived. The Foundation reviews applications electronically; therefore **anything not submitted online will not be reviewed.**

General Timeline:

Application Deadline.....	1 st Wednesday of September
Review by Research and Research Training Committee.....	December
Review by Medical Advisory Council.....	January
Review by Board of Trustees.....	February
Applicant Notified.....	Early March
Earliest Start date.....	April 1

- Application must be typed in Times New Roman 12 or Arial 11 font.
- Margins should be no less than a half inch on each side.
- Each section may be numbered individually. Once all documents are uploaded to Proposal Central, the system will compile them into one PDF file in the correct order.
- The Research Plan section of the application, **including the Literature Cited**, is limited to ten (10) pages. Applications that exceed this page limit will not be reviewed.
- All signatures, on all parts of the application, must be in **BLUE INK ONLY**.
- See page 10 for a full list of Submission Guidelines.

REVIEW AND AWARD

All applications are evaluated either by CFF's Research and Research Training (RRT) Committee or by CFRT's Clinical Research Committee (CRC), depending on whether or not the proposal involves basic research or clinical research, respectively. The recommendations of the RRT and CRC are reviewed by the Medical Advisory Council (MAC) and the Board of Trustees for final approval and funding. Funding of awards is based on the priority score awarded each application and the recommendations of the RRT or CRC and MAC. Relevance of the proposed study to issues in CF is also considered in determining awards. All research awards are subject to observance of the regulations and policies of CFF related to that category of research support and are contingent upon the availability of CFF funds.

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

1. Insufficient information or documentation in proposal, including receipt of letters of reference after the deadline.
2. Inadequate statement of hypothesis, experimental design, or methods.
3. Failure of applicant to demonstrate awareness of and plans for coping with key problems and pitfalls associated with the undertaking.
4. Insufficient or improper controls, especially in human clinical studies. (For example, a particular hypothesis may necessitate a control group of individuals with lung diseases other than cystic fibrosis, staging of the severity of lung disease, or age-matched controls.)
5. Failure of applicant to describe potential relevance of the proposed study to issues in CF.
6. Failure of applicant to document the necessary skills or training to accomplish the goals of the proposal.
7. Failure of the candidate to meet all the criteria described in the policy statement for the award.
8. Failure of applicant to describe career goals as they may be related to a long-term commitment to CF research and care.

In general, a successful candidate will have:

1. Previous relevant research training.
2. Expertise in a related research technique.
3. A minimum of one manuscript or abstract accepted for publication.

Candidates who do not have adequate research training are encouraged to apply to the CFF Clinical Fellowship program.

INSTRUCTIONS FOR COMPLETING SPECIFIC APPLICATION COMPONENTS

- Application must be typed in Times New Roman 12 or Arial 11 font.
- Margins should be no less than a half inch on each side.
- Each section may be numbered individually.
- Do **not** password-protect or otherwise encrypt documents prior to uploading.
- The Research Plan section of the application, **including the Literature Cited**, is limited to ten (10) pages. Applications that exceed this page limit will not be reviewed.
- All signatures, on all parts of the application, must be in **BLUE INK ONLY**.
- See page 10 for a full list of Submission Guidelines.

FACE PAGES

The Face Page will be populated automatically with the application information (applicant's name, institution, title of application, etc.) entered into the Proposal Central website. Print the Face Page from the website for the hardcopy. It will include a second page with institution and contact information. **Sign the Face Page in BLUE INK ONLY.** Photocopied, stamped, or scanned signatures will not be accepted.

ABSTRACTS

Lay Abstract

Please provide a statement of **no more than 250 words** explaining the subject of the research proposal and its relationship to CF. This statement will be used to inform the non-scientific departments of CFF and the general public of the nature of this work. Please write in terms applicable to an informed lay readership.

Scientific Abstract

Please provide a statement of **no more than 250 words** explaining the subject of the research proposal and its relationship to CF. This statement will be used to inform the scientific community of the nature of this work.

Please note that the abstracts should be completed online. An Abstracts page will be generated from the information entered in Proposal Central and a PDF will be created as part of the application. To avoid confusion, do not upload a separate abstracts document to Proposal Central.

CRITIQUE RESPONSE

If the application is a resubmission, please provide a point-by-point response to the prior reviews. Be concise and succinct in the response.

BUDGET AND BUDGET JUSTIFICATION

Please complete the online budget summary in addition to a detailed budget and budget justification for all years of support requested (maximum of three years). Be sure that the detailed budget matches the online budget summary.

Detailed Budget

Personnel - At least 70% of the applicant's time must be devoted to research. If salary is supplemented by support from other agencies, the percent of salary requested must equal the percent time to be allotted to this project. Indicate dollar amounts separately for salary and fringe benefits. Fringe benefits may be requested if they are treated consistently by the applicant institution as a direct cost to all sponsors. If support is requested for a technician, identify the amount of time the technician will devote to the study. Explain other sources of funding for the salary and fringe benefits. **The total salary and benefits for the applicant cannot exceed \$76,000 per year.**

Equipment - List all items of minor equipment 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. Major equipment purchases of over \$5,000 are not allowable.

Supplies - Itemize supplies, such as glassware, chemicals, animals, etc., 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.

Travel - Describe the purpose of any travel. Funds for travel outside the North American continent are not permitted. Also note that requests for travel funds should be limited to \$750.

Other Expenses - Itemize other expenses by major categories, such as duplication costs, publication costs, computer charges, equipment maintenance, etc. Justify all items.

The maximum level of support available under this program is \$91,000 per year. CFF does not provide indirect costs on physician-scientist training awards.

Budget Justification

Use this page to describe the nature of costs listed in the “Detailed Budget.” Costs should be described in terms of major categories, such as Personnel, Consultants, Equipment, etc.

FACILITIES AVAILABLE

Describe the facilities and equipment available at the applicant’s organization that will be used for this project. 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. Use continuation pages, if necessary. Describe facilities in terms of relevant areas, such as laboratory, clinical, animal, computer, office, etc. Provide any additional information about the environment, including any support services available that will be utilized for this project.

BIOGRAPHICAL SKETCH

A biographical sketch in CFF format should be completed for all key project personnel, beginning with the **applicant, the Sponsor(s), and other key personnel**. CFF defines “key project personnel” as anyone with an advanced degree who will play an instrumental role in the accomplishment of the training or project. The complete Biographical Sketch should not exceed three (3) pages. Clearly identify the results of any previous CFF support (i.e., funding from other sources, journal articles, invited presentations, etc.). Prior publications relevant to the present application should be clearly identified. **NIH Biosketches are NOT accepted as CFF requires additional information.**

OTHER SUPPORT

Other Support pages should be completed for all key project personnel. List only current funding. There is no page limitation for other support.

PROOF OF CITIZENSHIP

Harry Shwachman Cystic Fibrosis Clinical Investigator Awards are restricted to individuals who are United States citizens or Permanent Residents. Proof of Citizenship or Permanent Residency must be provided (e.g., copy of passport, birth certificate, or Permanent Resident Visa).

NAMES AND ADDRESSES OF REFERENCES

Letters of reference/support must be submitted by the following:

- The Sponsor of the clinical fellowship training.
- The Research Sponsor for this award.
- The CF Center Director(s) at the sponsoring (or nearby) institution.
- The Chair of the applicant’s department at the sponsoring institution.

These letters should discuss the applicant's scientific and clinical abilities, interests, and potential. Letters from the Research Sponsor and Department Chair should also clearly describe the institution's commitment to the professional growth of the applicant. Other letters of reference may be submitted if the applicant chooses to request additional letters.

In the applicable section on Proposal Central, list the names and addresses, including e-mail addresses, of the individuals who have been asked to submit letters of recommendation. **The applicant should inform those individuals to submit the letters at least one (1) week prior to the application deadline.** This helps to ensure that the letters have been uploaded **before** the application must be submitted. Once the applicant has submitted his/her application, no further documents can be added on-line. Therefore, if the application is submitted prior to the Sponsor(s) or other Referee(s) uploading their letters, the Sponsor(s)/Referee(s) will be unable to do so.

Letters uploaded to Proposal Central should not be password protected or otherwise encrypted. Such encryption will cause errors in assembling a single-print PDF of the application. The applicant should inform the individuals writing letters to not include password protection on the documents.

Letters of reference are weighted heavily during the review. These letters must be submitted electronically through the Proposal Central website 1 week BEFORE the application deadline and the original letters must be sent directly to the Foundation from the referee.

PREVIOUS TRAINING AND FUTURE PLANS

The applicant must prepare a brief summary of his/her research and clinical fellowship training and future plans. This section should present the applicant's interest in and commitment to CF research and care, and to pursuing a career in academic medicine. This section should also be completed in conjunction with the sponsor and should outline the general plan for continued training of the applicant in CF-related research. Participation in supplemental course work and special seminars should be included.

RESEARCH PLAN

The Research Plan for this award is limited in length to 10 pages, **including the Literature Cited.**

In the Research Plan, include sufficient information to permit effective review without reference to previous applications. Information should be presented in a clear, concise manner, while being specific and informative.

- A. **Hypothesis and Specific Aims.** State concisely and realistically what the research described in the application is intended to accomplish during the period of the grant and/or the hypothesis to be tested. *Do not exceed one page.* **When preparing the specific aims, keep in mind the mission of the Cystic Fibrosis Foundation.**
- B. **Background and Significance.** Briefly describe the background of the present proposal. 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. In addition, the applicant should describe the relationship of the proposed work to his/her long-term career goals. Preference will be given to those applicants who have expressed an interest in a long-term career in CF-related research.
- C. **Preliminary Results.** If applicable, provide a detailed discussion of any preliminary results.
- D. **Experimental Design and Methods.** Provide a detailed discussion of the experimental design and methods to be used to accomplish the specific aims. Describe the protocols, including methods for new techniques, and explain potential advantages over existing methodologies. Discuss the data expected to be obtained and the means by which data will be analyzed and interpreted. If clinical studies are involved, provide details of the methods for patient selection and care. Discuss potential difficulties and/or limitations of the proposed procedures and alternative approaches to achieve aims. Point out any procedures, situations, or materials that may be hazardous to personnel or patients and the precautions to be exercised.

Experimental Design and Methods (for applicants proposing to carry out Clinical Research through this support mechanism). Provide a detailed discussion of the experimental design and procedures to be used to accomplish specific aims. Please discuss: study hypothesis; primary and secondary outcome measures; study design; study sample-inclusion and exclusion criteria; sample size estimates;* subject enrollment including age range; puberty status; gender distribution; randomization scheme if applicable; description of experimental procedures and schedule including a study time-line; drugs and dosage; measures of compliance; follow-up schedule including a time-line; drugs and dosage; measures of compliance; follow-up schedule including a time-line for full project up to three years; ascertainment of response variables: efficacy and safety, training, data collection, data monitoring and quality control; and a description of your proposed data analysis and statistical procedures for your hypothesis testing. Although no page limit is specified for this section, make every attempt to be concise and succinct.

***For sample size estimates,** please provide all estimates of means, standard deviations, rates or proportions used to calculate each of your sample size or power estimates. Please include in the statistical section whether you will use a one or two-tailed test, the power selected for such a test (if making a sample size calculation), and the reference for your sample size or power calculation. In instances of pilot studies where some of these parameters are unknown, we will accept your best estimates of the unknown parameters if preliminary data are not available, and if your calculation is a preliminary estimate before formal sample size can be calculated for a larger study. Please identify if you are making estimates from data or from personal estimates. This section must document access to adequate numbers of subjects. The number of CF patients in the participating CF Center(s), as well as the number in relevant control groups, must be specified. Discuss the potential difficulties and limitations of the proposed procedures and alternative strategies for achieving the aims. If the Sponsor(s) is not a CF Center Director or Co-Director, a letter of support from the Center Director is required. Please provide a copy of your institution's IRB approval and/or protocol with proposed patient consent forms.

- 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 grant 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 Research 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).

DATA SAFETY MONITORING PLAN (Required for Clinical Research projects)

In compliance with Federal regulations, all applicants must submit a general description of the Data Safety Monitoring Plan (DSMP) for any proposed study that places human subjects at more than minimal risk. A DSMP helps to ensure subject safety, as well the validity and integrity of the data. Furthermore, a DSMP allows for the monitoring of study data to assess whether or not an early termination is necessary for safety or efficacy reasons.

The extent of monitoring required for a study is dependent on the level of risk involved for the subjects, as well as the size and complexity of the study. CFFT-funded Phase III clinical trials must utilize a Data Safety and Monitoring Board (DSMB). In addition, CFFT recommends that investigators utilize a DSMB for any Phase I or II clinical trials that are:

- Multi-center;
- Blinded to the investigator;
- Conducted in an emergency setting;
- Use high-risk interventions, such as gene therapy or gene transfer; or
- Include particularly vulnerable study populations, such as pediatric patients.

Address the following areas in the DSMP:

Assessment of Risk (see table on following page) – Describe the level of risk the proposed research presents to subject participants and provide a detailed justification for the level of risk. Discuss who will monitor the study.

Anticipated Adverse Events and Grading Scale – Describe anticipated adverse events (AEs), including expected frequency and the grading scale to be used. Discuss plans for addressing AEs.

Reporting of AEs – Detail the plan for reporting AEs, including who shall be notified in the event an AE should occur.

Safety Monitoring Plan – Describe all tests, evaluations, and exclusion criteria that will be implemented to ensure and monitor the safety of human subjects. Discuss plans for stopping the study if necessary.

Safety Reviews – Describe the process for monitoring and reviewing subject safety data, including the frequency of such reviews. Include details as to who will perform the monitoring and plans for reporting. If utilizing a DSMB, provide a composition of the board, the functions of the board, the frequency of meetings, the reporting requirements, including AEs, and the procedure for interim reporting as necessary.

Minimal Risk	Low Risk	Moderate Risk	High Risk
<ul style="list-style-type: none"> • Study poses no more risk than expected in daily life (blood draw, physical exam, etc.); • Behavioral studies; • Nutritional studies; • Observational studies; • MRI studies; • Survey or questionnaire studies 	<ul style="list-style-type: none"> • Studies of normal volunteers using well-described research procedures (IV infusion, euglycemic clamp, etc.) • Studies which might meet requirements for minimal review but include special populations or invasive procedures; • Post-marketing study Phase IV drug or device, as defined by FDA 	<ul style="list-style-type: none"> • Subjects treated with placebo for a recognized disease; • Involves subjects with HIV/AIDS, hepatitis, or cancer on a treatment study; • Substantial risk (>5%) of a Serious Adverse Event originating from the underlying condition of the enrolled subject; • Phase I or II study with available safety data in humans; • Industry sponsored Phase III clinical trial 	<ul style="list-style-type: none"> • Involves an intervention or invasive procedure with substantial risk; • An investigator-initiated IND trial; • Implantation of device with an IDE; • Involves the use of a new chemical or drug for which there is little or no toxicology data in humans; • A gene therapy study or research involving recombinant DNA molecules (gene transfer); • Investigator-initiated multi-center trial • Investigator-initiated Phase III clinical trial; • Involves the manufacturing of agents on campus; • Study has provisions to waive consent in emergency circumstances; • Involves vulnerable populations (e.g. pediatric, pregnant, etc.); • Blinded Phase I and II trials

Research Involving Human Subjects

CF Foundation policy pertaining to the protection of individuals as research subjects requires that for each proposal submitted, the applicant 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 Department of Health and Human Services policies. This certification should accompany the application and **must** be received before activation of any grant. If approval does not accompany the application, there should be a statement in the application indicating that such approval is pending and the date when such approval is expected. **The IRB application must be submitted to the applicant institution BEFORE the CFF application deadline.** The approved certification should be submitted as soon as it is available.

Research Involving Recombinant DNA

All research involving recombinant deoxyribonucleic acid (DNA) techniques and human gene transfer supported by CFF must meet the requirements contained in the document *NIH Guidelines for Research Involving Recombinant DNA Molecules* (revised September 2009). This publication and announcements of modifications and changes to the *NIH Guidelines* are available from the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD, 20892-7985 or accessed on-line at http://oba.od.nih.gov/rdna/nih_guidelines_oba.html. The purpose of the *NIH Guidelines* is to specify practices for the construction and handling of: (i) recombinant deoxyribonucleic acid (DNA) molecules, and (ii) organisms and viruses containing recombinant DNA molecules. As defined by the *NIH Guidelines*, recombinant DNA molecules are either: (i) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell; or (ii) molecules that result from the replication of those described in (i) above.

Many types of studies involving recombinant DNA are exempt from the *NIH Guidelines* while others are prohibited. The applicant organization is required to establish and implement policies that provide for the safe conduct of the research in full conformity with the *NIH Guidelines*. This responsibility includes establishing an Institutional Biosafety Committee to review all recombinant DNA research to be conducted at or sponsored by the applicant organization, and to approve those projects it finds are in conformity with the *NIH Guidelines*.

CF Foundation policy pertaining to recombinant DNA research requires that the grantee institution certify in writing that an institutional committee has reviewed and approved the procedures involving recombinant DNA in accordance with the *NIH Guidelines*. This certification should accompany the application and **must** be received before activation of any grant. If approval does not accompany the application, there should be a statement in the application indicating that such approval is pending and the date when such approval is expected. **The recombinant DNA application must be submitted to the grantee institution BEFORE the CFF application deadline.** The approved certification should be submitted as soon as it is available.

Research Involving Animals

Grant applications submitted to CFF involving the use of animals must meet the guidelines of the National Institutes of Health, U.S. Public Health Service, which require that all proposed studies be reviewed and approved by an Institutional Animal Care and Use Committee (IACUC). Written documentation of approval should accompany the application and **must** be received before activation of any award. If approval does not accompany the application, there should be a statement in the application indicating that such approval is pending and the date when such approval is expected. **The IACUC application must be submitted to the applicant institution BEFORE the CFF application deadline.** A copy of the IACUC approval should be submitted as soon as approval is received. In addition, CFF grantee 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.

Additional Material

- ❑ Up to four reprints of the applicant's or Sponsor(s)'s work relating to the general area of research in the grant proposal may be uploaded in PDF format
- ❑ Letters of Collaboration (if applicable)
- ❑ For clinical research, a copy of the IRB application and patient consent forms
- ❑ Other written confirmation of organizational assurances (if applicable)
- ❑ Other materials pertinent to the grant proposal, not already described

Keep in mind that extensive appendix material may not be reviewed. Please upload only the most relevant documents.

SUBMISSION GUIDELINES

Application Deadline: First Wednesday of September at 5:00pm (Eastern Time)

Applications must be submitted at Proposal Central: <https://proposalcentral.altum.com/>. The signed, original Face Page should be returned to CFF and **postmarked** by the same date. Late applications will not be accepted and the deadline will not be waived. The Foundation reviews applications electronically; therefore **anything not submitted online will not be reviewed**.

- Application must be typed in Times New Roman 12 or Arial 11 font.
- Margins should be no less than a half inch on each side.
- Each section may be numbered individually. Once all documents are uploaded to Proposal Central, the system will compile them into one PDF file.
- Do **not** password-protect or otherwise encrypt documents prior to uploading.
- The Research Plan section of the application, **including the Literature Cited**, is limited to ten (10) pages. Applications that exceed this page limit will not be reviewed.
- Original letters of recommendation and support should be submitted directly to the CFF and uploaded to the Proposal Central website **by the referee 1 week before** the application deadline.
- All additional material (letters of collaboration, IACUC/IRB/IBC approvals, publications, etc.) should be scanned and uploaded as PDF appendix material online.
- The Face Page must be signed in **BLUE INK ONLY** and returned to CFF:
**Cystic Fibrosis Foundation
Grants and Contracts Office
6931 Arlington Road
Bethesda, MD 20814**

To submit the electronic application, please visit: <https://proposalcentral.altum.com/>. **REMEMBER TO CLICK “SUBMIT” WHEN THE APPLICATION IS FINISHED.** An e-mail will be generated automatically from Proposal Central confirming that the application has been successfully uploaded. **If you DO NOT receive a confirmation e-mail, please contact Proposal Central (see e-mail address and telephone number below).**

Do not submit an incomplete application. An application will be considered incomplete if it fails to comply with instructions or if the material is insufficient to permit adequate review.

Revisions, insertions or appendices to applications will not be accepted after the receipt date unless agreed to by CFF’s Grants and Contracts Office. Even if a part of an application is approved for late submission, there is no guarantee that the application will be reviewed. Only Human Subjects Certification, Use of Animals Certification, and Recombinant DNA Approval will be accepted apart from the body of the grant application if they are not available at time of submission.

Requests to submit supplemental data must be received before November 1st, and even if accepted, review of these items is not guaranteed.

For questions regarding application contents:

E-mail CFF’s Grants and Contracts Office at grants@cff.org or call (301) 951-4422.

For questions regarding the application website:

E-mail Proposal Central at pcsupport@altum.com or call (800) 875-2562 during business hours (Monday – Friday, 8:30am – 5:00pm Eastern).

ELECTRONIC APPLICATION CHECKLIST

Application Deadline: First Wednesday of September at 5:00 pm (Eastern Time)

Applications must be submitted at Proposal Central: <https://proposalcentral.altum.com/>. The signed, original Face Page should be returned to CFF and **postmarked** by the same date. Late applications will not be accepted and the deadline will not be waived. The Foundation reviews applications electronically; therefore **anything not submitted online will not be reviewed.**

- Face pages which include:**
 - Original Signatures***
 - Principal Investigator
 - Sponsor(s)
 - The Official authorized to sign on behalf of the Sponsoring Institution
 - Applicant/PI information
 - Organization Assurances
 - Human Subjects Certification - Minimal patient risk only
 - Recombinant DNA Biosafety Certification
 - Research Involving Animals Certification
 - Complete Institution and PI Contact information, including correct mailing address
- Research Plan, Supporting Documents and Appendix**
 - Abstracts
 - Critique Response (when applicable)
 - Budget and Budget Justification
 - Facilities Available
 - Biosketches for all key personnel (use CFF format)
 - Other Support for all key personnel (use CFF format)
 - Proof of citizenship (copy of passport, birth certificate, or Permanent Resident Visa)
 - Previous Training and Future Plans
 - Names and Addresses of References
 - Letters of Support and Recommendation
 - Electronically submitted **by the Sponsor/Referee** through the Proposal Central website
 - Original sent **by the Sponsor/Referee** directly to the Foundation
 - Research Plan
 - Specific Aims
 - Significance
 - Preliminary Results (when applicable)
 - Experimental Design and Methods
 - Consultants/Collaborative Arrangements
 - Literature Cited
 - Data Safety Monitoring Plan (required for Clinical Research projects)
 - Appendix
 - Letters of collaboration (when applicable)
 - For clinical research, a copy of the IRB approval, protocol, and patient consent forms
 - Written confirmation of other organizational assurances (when applicable)
 - Reprints

* CFF does not expect signatures to be included in the electronic copy, but the submitted hardcopy must include **original** signatures on the Face Page **in blue ink**. Photocopied, stamped, or scanned signatures will not be accepted.