EPILEPSY THERAPY PROJECT – NEW THERAPY COMMERCIALIZATION GRANT & SEAL OF EXCELLENCE AWARDS

Founded in 2002 by Warren Lammert and Orrin Devinsky, MD, the Epilepsy Therapy Project (ETP) merged with the Epilepsy Foundation in 2012. The ETP vision is to foster innovation and support scientific advancements that could result in new treatments for people with epilepsy. Our goal is to accelerate therapies onto the market – in a timeframe that matters!

ETP provides new therapy commercialization grants (NTCG) to support later-stage development projects past proof of concept stages. For projects that are beyond the resources of the Epilepsy Foundation, applicants can also apply for an Epilepsy Innovation Seal of Excellence award (SEAL). The SEAL is not a grant program but an official housekeeping seal of approval that a team can use to generate further venture capital interest. The SEAL awards undergo the same application and review process as the NTCG.

Areas of interest for the Foundation include:
- Novel approaches to treatment.
- Platform technology to advance screening techniques that can be utilized by multiple laboratories, including utility of techniques for early proof-of-concept trials.
- Adaptation of treatment in development for another therapeutic area to assess utility for epilepsy (while maintaining patent protection).

This document summarizes the area of requirements for grant submission and considerations for applicants and reviewers. Applicants are strongly advised to read through the entire document before starting an application. If there are any additional questions, please contact grants@efa.org.

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New Therapy Commercialization Grant-at-a-Glance

These grants support the development of more effective therapies by serving as a catalyst for moving innovative therapies from the laboratory to the patient. Note that preference will be given to proposals that already have a commercial partner engaged to assist with development and to proposals that have committed or matched funding from the sponsoring institution, commercial partner or other third-party source. For the New Therapy Commercialization Grants, applicants must demonstrate background work beyond the proof of concept / basic science discovery stage.

We support projects spanning diagnostics and devices to small molecules and biologics. For programs that seek to develop diagnostics and/or devices, projects must be in later stage feasibility testing or in the proof of value stage (i.e. there should be a minimal viable product (MVP) prototype with a product IFU (instructions for use) to be competitive. For programs that seek to develop potential drugs through small molecules and biologics, there must be at least one lead compound identified, which may be at the pre-IND (Investigational New Drug application) to be competitive for a New Therapy Commercialization Grant. Investigators of drugs are strongly advised to have their compounds screened, as appropriate, by the NINDS ETSP Program prior to applying.

**Financial Support:** up to $350,000 for a maximum of 2 years.

**Deadline for Submission:** LOI due **July 20, 2018.** Full Application due **Oct 1, 2018**
Submission System: Applications are submitted electronically via the proposalCentral system: 
https://www.proposalcentral.altum.com. For help with electronic application process, please contact the help desk for proposalCENTRAL: pcsupport@altum.com or 1-800-875-2562,

Eligibility: Investigators must hold a relevant advanced degree (MD, PhD, MS, PharmD), and have completed all research training appropriate to the project proposed. Investigators may come from public and/or private sectors. We also consider international applications.

Epilepsy Innovation Seal of Excellence Award-at-a-Glance:
This comes with no award dollars but an official housekeeping seal of approval that can be used to generate further venture capital funds. The deadlines and application process for the Seal are similar to the NTCG process.

Deadline for Submission: LOI due July 20, 2018. Full Application due Oct 1, 2018
Submission System: Applications are submitted electronically via the proposalCENTRAL system: 
https://www.proposalcentral.altum.com. For help with electronic application process, please contact the help desk for proposalCENTRAL: pcsupport@altum.com or 1-800-875-2562,

Eligibility: Investigators must hold a relevant advanced degree (MD, PhD, MS, PharmD), and have completed all research training appropriate to the project proposed. Investigators may come from public and/or private sectors. We also consider international applications.

Components of LOI Submission
The Letter of Intent (LOI) for a New Therapy Commercialization Grant are submitted via proposalCENTRAL as a PDF file. The PDF file that is uploaded must have the following eight sections completed:
1. Title of proposed project (maximum 75 characters)
2. Principal Investigator (name, title, affiliation, address, telephone, email address)
3. Co-Investigators (names, titles, affiliations) (only key co-PIs)
4. Anticipated total budget. Budget should not exceed $ amount corresponding to program. Justify, including funding from other sources.
5. Brief summary of project goals and plans/approaches (not to exceed ½ page)
6. Explanation of how the application fits with the purpose of the grants program (not to exceed 1 paragraph)
7. Brief description of intellectual property position and potential for commercialization (one paragraph)
8. Brief description of what is unique about the project, and how it compares to any competitor (2 sentences)

LOI Submission for Revised Proposals (resubmissions)
For revised proposals and resubmissions, one needs to address changes to items 5-8 in the LOI. Specifically, the applicant should highlight the different changes from previous application that addresses key critiques (not to exceed 1 page)
LOI Format
Must not exceed 2 pages, inclusive of all information listed above (#5, #6, #7)

- Minimum 10-point font
- Convert LOI document to a PDF and then upload in proposalCENTRAL

LOI Submission
Submit the completed LOI through proposalCENTRAL: https://proposalcentral.altum.com. Once there, click ‘Applicants: Click Here to Login, Register to Apply’, and setup an account Click on ‘Validate’ to make sure all required fields have been filled in Click on the ‘Submit’ link to submit LOI in proposalCENTRAL.

LOI Applicant Notification
LOIs will be reviewed within approximately two weeks after the LOI submission deadline, at which time Principal Investigators / Contact People will be notified if a full proposal is or is not invited for submission for a full review.

Components of Full Grant Submission FOR NTCG and SEAL
There are eight required components to the research grant submission, which are outlined below.

1. Cover Page
2. Summary Statement
3. Commercialization Potential
4. Research Proposal & References
5. Biographical Sketch
6. Budget Justification & Other Support
7. Facilities
8. Organizational Assurances
9. Supplemental Materials (optional)

Part 1: Cover Page
The Cover Page should include the following information:

a. Title of proposed project (maximum 75 characters)
b. Institutional approvals for work involving humans or animals (project number and date of approval)
c. Principal Investigator (name, titles, affiliation, address, telephone, email address)
d. Key Co-Investigators (names, titles, affiliations)
e. Contact person if other than Principal Investigator (name, address, telephone, email address)
f. Institutional officers (financial officer and grant administrators) responsible for the proposal and award
Part 2: Summary Statement

A summary statement will become public information, therefore, do not include any proprietary or confidential information. The statement is maximum one page and should include the following 3 sections.

a. What is unique and significant from a therapeutic perspective about the project, how will it lead to new treatments for epilepsy, and how it compares to any competitor
b. What proof of principle or indication of efficacy and safety currently exist
c. A project summary written in lay language for consumers (approximately 50 words)

Part 3: Commercialization Potential

This section is maximum one page, and the following three items need to be discussed:

a. Description of intellectual property position
b. Potential pathway for commercialization, including potential (contacted) or actual commercial partners
   c. Timeline for work proposed; estimated time to reach patients for clinical study and as a commercially available therapy

Confidential information should NOT be sent to the Epilepsy Foundation or provided in any grant application without advance discussion with the Epilepsy Foundation and only with appropriate confidentiality agreements. Please look at the reviewer considerations section for more information on what should be addressed.

Part 4: Research Plan & References:

The Research Plan is maximum 7 pages for first time submitters. Research plan sections include: specific aims, research strategy, and references. These sections are modeled after the NIH application process, and we recommend using their guidelines to a successful application: https://www.niaid.nih.gov/grants-contracts/write-research-plan#A1.

See the table below for a breakdown of the sections. We also recommend looking at the reviewer considerations to ensure that all questions are addressed during peer review to ensure a successful application.

<table>
<thead>
<tr>
<th>Section of Application</th>
<th>What this Section Addresses</th>
<th>Page Limit</th>
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<tbody>
<tr>
<td>Specific Aims</td>
<td>State concisely the goals of the proposed research and summarize the expected outcome(s),</td>
<td>1 Page</td>
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<td>including the impact</td>
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</tbody>
</table>
that the results of the proposed research will exert on those impacted by epilepsy.

**Research Strategy**

A description of the rationale for your research and experiments. Please organize this section into 3 main headers: Significance, Innovation, & Approach.

a. **Significance:** Describe how successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive the epilepsy field? What is the rationale for this strategy?

b. **Innovation:** How does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?

c. **Approach:** (most important section: emphasize what will be done during the first year). Describe the key Go / No Go decision points and specific milestones. (Note: grant funding will be based on achieving milestones). Please include a Sample size (as needed) and statistical analysis plan

Please look at the [reviewer considerations](#) section to ensure a more competitive application. Preliminary studies are encouraged but not required.

**References**

Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Make sure that only bibliographic citations are included.

**Part 5: Biographical Sketch**

Biographical Sketches are required for the applicant and all listed key personnel. The Biographical Sketch must not exceed four (4) pages for each person listed as key personnel. Each Biographical Sketch should provide the following information about each key person, starting with the applicant:

**A. Positions and Honors.** List in chronological order previous positions, concluding with your present position. List any honors. Provide a brief explanation if there has been any changes to your
primary field of interest and/or career gaps due to personal or professional circumstances that may have affected your scientific advancement or productivity.

B. Selected peer-reviewed publications (in chronological order). Do not include manuscripts submitted or in preparation; abstracts or posters. Please choose selected publications based on most recent, importance to the field, and/or relevance to the proposed research. Please keep in mind the 4-page limit.

Note that applicants can use the NIH biosketch template for submission.

Part 6: Budget Justification & Other Support:

Budget: Applicants may request up to $350,000 over a one to two year period. These grants support direct costs of research for programs that have progressed beyond the basic science discovery stage. Enter detailed budget costs.

Funds may NOT be allocated for travel, administrative purposes, or equipment. Salary for pre/post-doctoral trainees should be justified based on full-time work on this proposal. Include Go/ No Go decision points and milestones, and specific milestones in the budget. As grant funding will be based on achieving milestones, this section is key and an important part of the funding decision.

Other Support: Please provide the title, role in grant, percent effort, amount of funding and years of current and pending support for each grant (including SBIR, STTR, RAID). Include all non-governmental funding (e.g. CURE, Epilepsy Foundation, American Epilepsy Society, other foundations) for work related to this proposal (past, present, pending) and how this impacts Intellectual Property.

Information should be provided in the format shown in the Support template. No page limit applies for Support information. Note that support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual’s research endeavors, including but not limited to research grants, cooperative agreements, contracts, and/or institutional awards. Please specify who the Primary Investigator is for all support listed.

The Epilepsy Foundation will not award funds to duplicate any work that is being supported by other funding agencies. Budgetary overlap is not permitted; however, scientific overlap will be evaluated on an individual basis. In cases of significant scientific overlap, a successful applicant will have the option to choose between the Epilepsy Foundation award and that of the other organization.

Part 7: Facilities:

Describe the institutional resources and facilities that are available or will be provided for the project. Specify the facilities to be used for the conduct of the proposed research. Indicate the performance sites and describe capacities, pertinent capabilities, relative proximity, and extent of availability to the project. List the most important equipment items already available for this project, noting the location and pertinent capabilities of each.
Part 8: Organizational Assurances:

All research funded by the Epilepsy Foundation must comply with federal requirements regarding the use of human subjects and animals in research. **It is recommended that applicants submit projects to the appropriate Review Board at the time of application or before.**

Human and/or Animal Subjects/Tissues

When human subjects or tissues are to be used in a research project, it is the responsibility of the grantee to ensure that the project receives approval from his/her Institutional Review Board. A copy of that Board’s current approval notice and a copy of the patient informed consent form should be submitted with the application if they are available. If awarded a grant, these documents must be submitted before funding can begin.

Indicate on the electronic application the institutional OHRP Assurance Number, as well as, the individual proposal IRB status — “approved”, “pending”, “exempt” or “not applicable”. If approved, please provide the corresponding date of approval on the electronic application. If “exempt” from IRB approval within your institution, place “exempt” and the date the exemption was approved.”

When animals and/or animal tissues will be used, it is the responsibility of the grantee to ensure that the project receives approval from the Institutional Animal Care and Use Committee. If available, a copy of these documents should be submitted with the application. If awarded a grant, these documents must be submitted before funding can begin.

Epilepsy Foundation Policy on Use of Animals in Research

All entities that receive funding from the Epilepsy Foundation must adhere to the following principles:

1. Animals shall be used in biomedical research only when no other means of obtaining scientifically sound, valid, and useful results are available.
2. The minimum number of appropriate animals required to obtain and validate results shall be used.
3. The acquisition, care, and use of animals must be in accordance with all applicable federal, state and local laws and regulations.
4. Certifications must be received from research facilities prior to being approved for a research grant that the facility(ies), its researchers, and employees adhere to the Animal Welfare Act, National Research Council *Guide for the Care and Use of Laboratory Animals*, and any appropriate U.S. Department of Agriculture or National Institutes of Health regulations and standards.
5. In cases requiring the death of an animal, only the most appropriate and humane form of euthanasia shall be used consistent with the purpose of the research.
Indicate on the electronic application the institutional Animal Welfare Assurance Number as well as the Institutional Animal Care and Use of Committee (IACUC) status – “approved”, “pending”, “exempt” or “not applicable”. If approved, please provide the corresponding date of approval on the electronic application.

**Part 9: Collaborators**

Include letters from key collaborators indicating the extent of their participation (no bio sketches). Specifying their planned contributions (list only investigators who will actively participate in the program, not merely mentor, advisor, or extra name). They should be uploaded in the ‘Upload Attachments’ section of proposalCENTRAL.

**Part 11: Supplementary Materials**

**Clinical Trial Protocols (if applicable)**

a. Investigators proposing a clinical trial should include the protocol in the supplementary materials. If another entity, such as a pharmaceutical company, is providing partial funding support or in-kind contribution to the study (such as study drug and/or placebo), please provide a letter of support detailing the agreed-upon funding or resources provided. For all other study types, supplementary materials are discouraged, but may be included as an Appendix, IF ESSENTIAL.

Note: Save and upload the Summary Statement, Commercialization Potential, Proposal, Bio Sketches, Collaborators Letters, and Supplementary Material as PDF files in the ‘Upload Attachments’ section.

**Part 12: Revised Proposal Content (For Resubmissions Only)**

Provide a response to the critiques received from the earlier submission.

**Tips for a successful Epilepsy Therapy Project NTCG application**

Here are some helpful tips to improving your application for an ETP commercialization grant:

- Include Go/ No Go decision points and milestones in the research plan, and specific milestones in the budget. As grant funding will be based on achieving milestones, this section is key and an important part of the funding decision.

- Detailed budget and justifications for 1st year (and 2nd year, if needed). Budget should not exceed $350,000 over a two-year period. Justify, including funding from other sources.

- If another entity, such as a pharmaceutical company, is providing partial funding support or in-kind contribution to the study (such as study drug and/or placebo), a letter of support detailing the agreed-upon funding or resources provided. This letter should be uploaded in the ‘Upload Attachments’ section of proposalCENTRAL.
• **Note that 1:1 matching grants are encouraged**, and preference will be given to proposals that already have a commercial partner engaged to assist with development and to proposals that have committed or matched funding from the sponsoring institution, commercial partner or other third party source.

• **Programs that seek to develop potential drugs** should have identified at least one lead compound, which may be at the pre-IND stage, in order to be competitive for a New Therapy Commercialization Grant. Investigators of drugs are strongly advised to have their compounds screened, as appropriate, by the **NINDS ETSP Program**. Investigators are expected to have an established record of achievement in the area. Full intellectual property (IP) rights (composition of matter) are preferred over method of use IP.

• **Clinical programs** must have a reasonable protocol and sample size to assure that the results will be meaningful; studies of patients should describe the type of seizure/epilepsy that will be investigated. Investigators proposing a clinical trial should include the protocol in the application materials. If another entity, such as a pharmaceutical company, is providing partial funding support or in-kind contribution to the study (such as study drug and/or placebo), please provide a letter of support detailing the agreed-upon funding or resources provided. Device programs should present novel concepts for treatment.

**Review Considerations:**

<table>
<thead>
<tr>
<th>Components of Review</th>
<th>Considerations</th>
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<tr>
<td><strong>Significance</strong></td>
<td>Does the project address an important problem or a critical barrier to progress in the epilepsy field?</td>
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<td>If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved?</td>
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<td>How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive the epilepsy field?</td>
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<td>How does the grant fit with the purpose of this Epilepsy Therapy Program, getting new therapies</td>
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<tr>
<td>Question</td>
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<td>to people with epilepsy faster – in a timeframe that matters?</td>
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<tr>
<td>Investigator</td>
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<td>Are the PI, collaborators, and other researchers well suited to the project?</td>
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<td>Have they demonstrated an ongoing record of accomplishments that have advanced their field(s)?</td>
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<td>If the project is collaborative or multi-PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?</td>
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<tr>
<td>Innovation</td>
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<tr>
<td>Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions?</td>
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<tr>
<td>Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?</td>
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<tr>
<td>Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?</td>
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<tr>
<td>Approach</td>
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<td>Is the research project well-conceived, with clear hypotheses, outlined milestones and clear go/no go decisions points?</td>
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<td>Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed?</td>
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<td>Are potential problems, alternative strategies, and benchmarks for success presented?</td>
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<td>If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?</td>
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<td>What is the probability of success? Can this get to patients?</td>
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**Commercialization Potential**

<table>
<thead>
<tr>
<th>What is the Intellectual Property Strategy &amp; Status?</th>
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<tr>
<td>Does the applicant discuss intellectual property aspects and associated actions of the applicant’s technology licensing office if relevant?</td>
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<tr>
<td>Does the applicant provide tangible evidence of institutional or company support if appropriate?</td>
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<td>Does the applicant identify any connections with potential implementation partners?</td>
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<td>Would the awardee have Freedom to Operate?</td>
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<tr>
<td>What is the Investment Potential &amp; Likelihood of Ongoing Funding Support? (i.e. can it get to patients)</td>
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**Environment**

<p>| Will the scientific environment in which the work will be done contribute to the probability of success? |
| Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? |</p>
<table>
<thead>
<tr>
<th>Additional Review Criteria</th>
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<tr>
<td>As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit and in providing an overall impact score, but will not give separate scores for these items.</td>
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<tr>
<td><strong>Budget:</strong> Is the budget reasonable? If another entity, such as a pharmaceutical company, is providing partial funding support or in-kind contribution to the study (such as study drug and/or placebo), is there a letter of support detailing the agreed-upon funding or resources provided?</td>
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<tr>
<td><strong>Clinical Trials (if applicable):</strong> Is a protocol and sample size calculation described, is it clear what clinical population and type of seizure/epilepsy will be investigated. What is the data safety monitoring plan? If no protocol is included, the clinical trial proposal must be triaged.</td>
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<tr>
<td>• Protections for Human Subjects</td>
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<td>• Inclusion of Women, Minorities, and Children</td>
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<td><strong>Additional comments (if applicable):</strong></td>
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<tr>
<td>Vertebrate Animals</td>
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<tr>
<td>Biohazards</td>
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<td>Resubmission</td>
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Application Formatting Requirements

All applications must adhere to the following language and format requirements. Please note that if the guidelines outlined above are not followed, the application will be administratively triaged and will not receive a review.

File Size
Limit the file size of each uploaded attachment to 3-4 MB.

Images and Text Formatting
Do not use text boxes.

1. The applicant’s name should always be in the top ‘HEADER’ portion. The header information should carry forward to subsequent pages in the template.

2. When incorporating figures into the text of your application document(s), follow these steps:
   a) Save your figures as individual .jpg or .gif files. Make sure your figures are not inserted into a text box. Do not use other graphic file types (e.g., .tif).
   b) In your MS Word Research Plan document, select “Insert>Picture>From File” in the “Insert” menu. Select the .jpg file you created, and click on the “Insert” button.

3. Type size limitations must be observed throughout the application. Use Arial 11-point size font only. Figure legends, footnotes, and aspects of charts and tables may be smaller in font size, but must still be clear and legible.

4. Margins, in all directions, must be at least 1/2 inch.

5. Be consistent with font styles and indentation.

Other Requirements

1. Use English only and avoid jargon and unusual abbreviations.

2. Do not include your social security number or passport number in your application.

Starting an Epilepsy Foundation Electronic Grant Application

Applicants applying for any Epilepsy Foundation award must begin their application by registering as a proposalCentral user.
Completing an Electronic Application

Begin your application submission process by creating a proposalCentral account or by logging in with your current pC account if you had previously been registered as either a reviewer or an applicant (see above).

1. Log onto proposalCentral
2. Select the appropriate application from the list of Epilepsy Foundation funding opportunities.
3. Click the Apply Now link to gain access to the application template.
4. Complete each of the proposal sections listed in the online application
5. Remember to select “Save Draft” regularly throughout the online application to ensure that your work is saved.
6. Click on the Additional Attachments link and download the appropriate supplemental template.
7. To complete the online submission, click the “Validate” in the Navigation Menu.

Epilepsy Foundation Templates

The Proposal Attachments section of the application contains downloadable files. The files include templates and instruction documents. Click the download link to save a template to your computer. You will complete each template offline. Use MS Word or MS Excel (depending on the template) to complete the template documents, then convert each file to PDF and upload the completed attachment files to your online application (see below for more information).

Please note that PDF proposal attachments should not be locked, password encrypted or protected.
Please confirm this before uploading to your application.

Some of the files you will download are required attachments. All required attachments will be indicated as such. Once you upload a completed required template, the template name will display in the “Current List of Uploaded Attachments” menu. The “Validate” link, located in the gray navigation menu and available from every online page of the online application, can also serve as a tool for you to check to ensure that at least one of each of the required attachments is included in your application.

Uploading Completed Templates – Once you have converted your application template to PDF, you must then upload the file(s) to your online application. Complete the following steps:
1. Open your application in proposalCentral and navigate to the Proposal Attachments section page
2. Enter a description of the file in the Describe Attachment field
3. Select Appropriate Attachment Type from the drop-down menu (e.g., Biosketch, Other Support)
4. Click the Browse button and choose your PDF, then upload the attachment

The file is now attached to the application and should now be listed in the Uploaded Attachment section. Two links are available in each row of an uploaded attachment: DEL (delete) and SHOW. Del allows you to delete the file, if necessary, and Show opens the uploaded file. It is strongly recommended that you open and review your uploaded file.

If, for any reason, you wish to modify the file, make the revisions in the original document (offline), convert the updated file to PDF and attached the revised file to the application. Delete previously submitted versions of the file.

Validation and Final Submission

To submit the final application, you must first validate your application to ensure that all required files are attached and that all required entries on all pages of the application have been completed as required. Click “Validate” link and the “Submit” link to submit your application to your Research Office contact (RO).

**Special Note:** The final submission of your proposal to the Epilepsy Foundation, via Proposal Central, automatically indicates to the Epilepsy Foundation that the PI and his/her administrative and financial officials, sponsors, and/or department heads certify that the statements within their Epilepsy Foundation proposal are true, complete, and accurate to the best of their knowledge, and accept the obligation to comply with Epilepsy Foundation terms and conditions if the grant is awarded as a result of the application. It further certifies that they are aware that any false, fictitious, or fraudulent statements or claims may subject the PI and the PI’s officials to criminal, civil, or administrative penalties.