



Clinical Research Training Apprenticeship

BACKGROUND AND PURPOSE

The Epilepsy Foundation (EF) seeks to advance the careers of clinical health care professionals committed to the care of individuals with epilepsy and improving their lives through research. In keeping with this goal, the Foundation will award two fellows for a one-year mentored Clinical Research Training Apprenticeship.

Applicants should be accepted into an epilepsy fellowship at a level 3 or 4 epilepsy center in the United States. They may apply for this grant for either their first or second year of fellowship. To apply for this grant, they must seek out a program that is actively involved in a large clinical research endeavor in epilepsy, and identify a mentor who is involved in the project. The applicant must identify their role in the project that will lead to a publication or independent scholarship related to the project (e.g. analysis of a patient subset, assessment of effectiveness of methodology, determination of study recruitment effectiveness and ways to improve it). Trainees will be expected to be fully active in the American Epilepsy Society's EpiPORT (Epilepsy-Patient Oriented Research Training) program, attend the Pipeline or AEDD meeting, and attend the AES annual meeting and participate in the Fellows Program.

The individualized training program may consist of both didactic training and a supervised research experience that is designed to develop the necessary knowledge and skills in the chosen area of research and foster the career goals of the candidate. This fellowship program is also viewed as a way for awardees to develop sufficient scientific skills and preliminary data to compete successfully for more long-term support (e.g. grants from the NIH).

The Clinical Research Training Apprenticeship awards \$25,000 for one year for salary plus \$10,000/year towards classwork and travel to appropriate meetings. Funding for the fellowships is provided by the Epilepsy Foundation, and the award will be administered by AES.

2016-2017 APPLICATION DEADLINES AND AWARD DATES

- August 15, 2016: Application submission opens through proposalCENTRAL
- October 5, 2016: Letters of Intent due^{1,2}
- November 30, 2016: Applicants invited to submit full proposals³
- January 31, 2017: Full proposals due
- April 28, 2017: Awards announced
- July 1, 2017: Earliest start date⁴

APPLICATION POLICIES

1. Prior unfunded applicants may reapply, but all applications will be treated as new submissions.
2. An individual may only serve as the primary mentor for one application submitted for a mentored award supported or administered by the American Epilepsy Society (AES). An individual may not apply for a Junior Investigator Research Award and also be listed as the primary mentor on a proposal for a mentored award. More than one application may be submitted from a single institution, but final funding decisions will take into account a preference to limit multiple awards to one institution.
3. Only applicants with an approved Letter of Intent (LOI) are eligible to submit a full proposal.
4. Applicants may request a delay in the start date of up to 3 months.

ELIGIBILITY

To be eligible to apply for a Clinical Research Training Apprenticeship, an applicant must:

1. Hold a Doctor of Medicine, Doctor of Philosophy, Doctor of Science, or equivalent degree. The eligibility of people holding other doctoral-level degrees (ex., PharmD, Doctor of Nursing) may be considered by the Foundation's Research Council based on the merit of the proposal;
2. Be a clinical fellow at a level 3 or 4 epilepsy center that is actively involved in a large clinical research endeavor in epilepsy in which the Trainee may be involved, and have an identified mentor with research experience.
3. Have an acceptable research plan directed toward the purpose of the Foundation's Research Program; and
4. Have access to institutional resources to conduct the proposed research project.

*Academic faculty holding the rank of Instructor, Adjunct Professor, Research Assistant, Assistant or Associate Professor are not eligible, nor are graduate or medical students, medical residents, permanent government employees, or employees of private industry. **Note that some fellowship programs appoint second year fellows as clinical instructors; these individuals in the second year of a fellowship ARE eligible to apply.**

Applicants whose research will involve patient care or direct involvement with patients must have completed all residency training *and* be licensed to practice medicine at their institution.

U.S. citizenship is not required; however, research must be conducted in the U.S.

Applications from women, members of minority groups, and people with disabilities are especially encouraged to apply.

SELECTION

Applications are evaluated based upon the quality of the proposed research training program; the applicant's qualifications; the preceptor's qualifications; and the adequacy of clinical training, research facilities and other epilepsy-related programs at the institution.

The Epilepsy Foundation anticipates the research experience of the applicant pool for Clinical Research Training Apprenticeship will be diverse. Thus one important criterion for selection will be the quality of the proposed training in relation to the research background of the applicant.

Successful candidates will spend at least 30% of their time dedicated to research training and conducting research. Applicants should state in the proposal the percentage of time he/she expects to devote to the research project.

Reviewers will evaluate applications based on the following criteria.

Applicant

- Is the applicant's academic record of high quality?
- Does the applicant have the potential and commitment to develop as an independent and productive epilepsy researcher?

Mentor

- Are the mentor's research qualifications (including successful competition for research support) appropriate for the proposed fellowship?
- Is the applicant's role in the project clearly defined?
- Is there a demonstrated ability and commitment of the mentor to assist in meeting these needs?
- Is there evidence of an outstanding track record in training by the mentor, including evidence of training outcomes that suggest that the research training provided by the mentor will foster a successful research career outcome for this applicant?

Research training plan

- Will the training plan help the applicant develop research skills?
- Is there a specific plan for applicant to attend national scientific meetings (especially the annual meeting of the American Epilepsy Society) and/or participate in appropriate networking activities?

Environment

- Are the research facilities, resources and training opportunities, including faculty capable of productive collaboration with the candidate adequate and appropriate?
- Is the environment for scientific and professional development of the candidate of high quality?

Should your application be deemed meritorious and eligible for funding by the peer review committee, your application may also be considered by members of the Epilepsy Leadership Council (ELC), (a coalition of non-governmental epilepsy organizations).

EPILEPSY FOUNDATION SUPPORT

Successful applicants receive an award in the amount of \$25,000 for one year for salary plus \$10,000/year towards classwork and travel to appropriate meetings.

The number of awards and level of funding is contingent upon the availability of funds. Quarterly payments are made to the institution for direct salary expense of the fellow and classwork and meeting travel costs ONLY. Travel must be conducted during the funding period. No indirect costs are provided. ***Submission of scientific and financial reports, no later than 30 days after completion of project, is a requirement.***

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.

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 fellowship 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.

APPLICATION INSTRUCTIONS

Letter of Intent: due by October 5, 2016

Letters of Intent (LOI) will be evaluated by the Epilepsy Foundation to assess the applicant's eligibility for the grant mechanism and consider the significance and feasibility of the proposed research, as well as the strength of the research training experience. **Only applicants who have submitted a LOI and receive approval are eligible to submit a full grant application.**

LOIs must be submitted through proposalCENTRAL (<https://proposalcentral.altum.com/>).

- Applicants who do not yet have an account with proposalCENTRAL will need to register as a new user and provide the requested professional profile information before proceeding.
- Once logged in as a user, go to the *Grant Opportunities* tab, and filter the list to display American Epilepsy Society Awards.
- Locate the line for *Epilepsy Foundation Clinical Research Apprenticeship (LOI)* and click on *Apply Now* to begin an application.

Required components of the LOI include the following sections to be completed as online forms or submitted as individual proposal attachments in PDF format. Additional instructions will be available on screen in proposalCENTRAL and within downloadable templates for proposal attachments.

Complete LOIs must be submitted through proposalCENTRAL by 5:00 p.m. Eastern time on October 5, 2016.

No applications, nor any parts of or updates to the application, will be accepted if submitted after the deadline or if sent directly to AES offices by electronic or U.S. mail.

1. Title Page:

- a. **Enter the title of your proposal.**
- b. **Categorize your research project according to the type of research conducted and particular relevance to specific forms of epilepsy.** Definitions for the categories are available at the end of these instructions. While multiple categories may be relevant to an individual project, please select the choice from each of the three category types that best fits your proposal. For research classification and epilepsy type, a secondary selection is optional.
- c. **AES Funding Partners.** In addition to AES and the Epilepsy Foundation, one or more funding partners may provide full or partial support for proposals in targeted research areas through this program

(see Contributing Partners above). Please confirm whether we may share your application with other relevant funding partners for consideration.

2. **Download Templates and Instructions:** This guidelines document and all proposal attachment templates can be downloaded here.
3. **Enable Other Users to Access This Proposal:** This screen allows you to give other users access to your grant application, if necessary.
4. **Applicant/PI:** Applicant information is pre-loaded from the applicant's PROFESSIONAL PROFILE. Double-check that the information is complete and correct. If not, click Edit Professional Profile to update.
5. **Institution and Contacts:**
 - a. Institution information is pre-loaded from the applicant's INSTITUTIONAL PROFILE. Double-check that the information is complete and correct. If not, click Edit Institutional Profile to update.
 - b. In the table provided, enter your primary mentor and co-mentor(s), if applicable.
6. **Abstracts and Keywords:**
 - a. Describe the proposed research project for both general (lay) and scientific audiences (1500 characters maximum for each abstract).
 - b. Please select keywords that describe the specific focus of your research. At least two keywords are required, and up to five are allowed. Please select keywords carefully, as they will aid in matching your application to appropriate reviewers.
7. **Proposal Attachments** (must be uploaded as PDFs; templates available for download)
 - a. **Applicant and mentor biosketches:** Provide using NIH-style format appropriate to applicant career stage. If co-mentors are proposed, include a biosketch for each co-mentor.
 - b. **Research and training summary:** Provide the following in no more than 2 pages. (Additional pages may be used for references, as needed.)
 - i. **Research Project Plan:** Outline the hypothesis and specific aims proposed, and briefly describe how the research will be carried out.
 - ii. **Training Plan:** Describe the clinical and research training you would receive during the fellowship term (including formal coursework) and how this training would contribute to your career goals. **Indicate the percent effort you will devote to research and training as part of this fellowship.**

Full proposals: due by January 31, 2017

Proposals must be submitted through [proposalCENTRAL](#). Only applicants who have submitted a LOI and receive approval are eligible to submit a full proposal. To begin your proposal, log in to proposalCENTRAL and select the MANAGE PROPOSALS tab, which contains a list of applications IN PROGRESS. The status of approved LOIs will appear as LOI: APPROVED. Click the EDIT button to begin preparing a full proposal.

Required components of the application include the following sections to be completed as online forms or submitted as individual proposal attachments in PDF format. ***Please read these full instructions carefully and plan in advance to ensure all components will be complete at the time you submit your proposal.*** Additional instructions will be available on screen in proposalCENTRAL and within downloadable templates for proposal attachments.

Complete applications must be submitted through proposalCENTRAL by 5:00 p.m. Eastern time on January 31, 2017. No applications, nor any parts of or updates to the application, will be accepted if submitted after the deadline or if sent directly to AES offices by electronic or U.S. mail.

1. Title Page:

- a. The APPLICATION TITLE, research classification information, and other responses submitted with your LOI will be pre-populated. Please confirm that the information is correct and update as needed.
- b. Enter the start and end date requested for your project. In general, the award term should be July 1, 2017-June 30, 2018. However, a delay of up to 3 months (beginning no later than October 1, 2017) in the start date is permitted if necessary.

2. Download Templates and Instructions: This guidelines document and all proposal attachment templates can be downloaded here.

3. Enable Other Users to Access This Proposal: This screen allows you to give other users access to your grant application, if necessary.

4. Applicant/PI: This information is pre-loaded from the applicant's PROFESSIONAL PROFILE. Double-check that the information is complete and correct. If it is not, click Edit Professional Profile to update.

5. Institution and Contacts:

- a. Institution information is pre-loaded from the applicant's INSTITUTIONAL PROFILE. Double-check that the information is complete and correct. If it is not, click Edit Institutional Profile to update.
- b. Enter the requested contacts in the table provided. Select the appropriate signing official and financial officer from the drop-down list or enter the email address of a new official and click on ADD. Complete the form, click on the SAVE or CLOSE WINDOW link, and the added official will be listed as the assigned signing official or financial/fiscal officer. Enter the correct contact and address to which award payments should be sent, if this proposal is selected for funding.

IMPORTANT: Please confirm with your institution that all information and contacts listed on this page are correct. If the application is selected for funding, this contact information will be used for grants administration correspondence and to issue payments.

6. Key Personnel: Indicate key personnel other than the applicant/PI who will contribute significantly to the execution of the proposal.

7. Letters of Reference: Use this section to request blind submission of a letter from a reference who is familiar with your research and training. Please start this process early to ensure submission by the application deadline. (One letter of reference is required; an additional letter is optional.) Do not use this section to submit the required letter from your mentor(s) for this application. The letter from the mentor must be submitted as a Proposal Attachment (see below).

8. Abstracts and Keywords: This information is pre-loaded from the LOI submission. Please review and make edits as needed.

- a. Describe the proposed research project for both general (lay) and scientific audiences (1500 characters maximum for each abstract).
- b. Please select keywords that describe the specific focus of your research. Two keywords are required, and up to five keywords are allowed. Please select keywords carefully, as they will aid in matching your application to appropriate reviewers.

9. Budget Period Detail: Use this section to provide a detailed budget for the fellowship year by listing costs under the headings provided.

- 10. Budget Summary and Justification:** The table on this page summarizes the information provided in the Budget Period Detail. Review and edit as needed. In the space below the table, provide a narrative justification for the costs in your proposed budget. (3000 characters maximum)
- 11. Organization Assurances:** Use this section to indicate use of human subjects, human tissue, or vertebrate animals, and to confirm institutional assurances. All assurances should be provided at the time of the application if available, and documentation must be provided before funding can begin for awarded proposals. See Award Policies above for more information.
- 12. Proposal Attachments:** Attachments must be uploaded as PDFs. Where noted, templates will be available for download on proposalCENTRAL. Select the appropriate attachment type and upload as instructed onscreen.
- a. **Signed Signature Page:** You will need to download this item in the SIGNATURE PAGE(S) section and have signed by the designated signing official (required) from the institution's sponsored research office (or equivalent), and then re-upload the signed page as a proposal attachment. The sections of the signature page will populate from the corresponding application sections above. Please make sure the fields on the Signature Page are complete before having it signed.
 - b. **Applicant and mentor biosketches:** Provide using NIH-style format appropriate to applicant career stage. If co-mentors are proposed, include a biosketch for each co-mentor. (template available if needed)
 - c. **Research Plan:** Please use the template provided and include the following elements: specific aims, background and significance, previous work directly related to this research (if available), research plan and methods. Use at least 11 pt font and at least ½ inch margins. (maximum 6 pages, not including references)
 - d. **Applicant Statement and Training Goals:** Please use the template provided and include the following elements. Use at least 11 pt font and at least ½ inch margins. (maximum 2 pages)
 - i. Describe your long-term career goals and your reason for choosing epilepsy as an area of specialized clinical and/or research training.
 - ii. Describe the clinical and research training you will receive during the fellowship term and how this training will contribute to your career goals.
 - iii. In the table provided, indicate the percentage of time you will spend in the activities identified. The total should not exceed 100%. (Applicants for the EF Clinical Research Apprenticeship must devote at least 30% effort to research and research training.)
 - iv. Describe your plans beyond the proposed fellowship period and how you imagine your training and research in the epilepsy field will continue. As applicable, discuss how the proposed fellowship will facilitate your transition to the next career stage.
 - e. **Other Support:** Please use the templates provided to list all other past (last 3 years), current, and pending support for the applicant's research and/or research training, and for the primary mentor's research. Other Support includes: all financial resources available in direct support of an individual's research and/or research training, including but not limited to research grants, research training fellowship awards, cooperative agreements, contracts, and/or institutional awards. Recognition awards, prizes, or gifts do not need to be included.
 - f. **Facilities Available:** Provide a profile of the institutional environment and the facilities available. Use at least 11 pt font and at least ½ inch margins. (no page limit, template available)
 - g. **Proposal Development:** Please identify the specific roles of the applicant and the mentor(s) in the development of this fellowship proposal. Use at least 11 pt font and at least ½ inch margins. (no page limit, template available)

- h. **Letter of support from the project mentor:** The mentor letter should describe the research training plan developed for the applicant, including the skills and techniques the applicant will learn as well as any classes, seminars, professional development activities, and opportunities to participate in conferences and other interactions with the research community. In addition, the letter should describe the applicant's qualifications for this fellowship and how the mentor's expertise and mentorship experience will contribute to his/her future success as a researcher. If one or more co-mentors are proposed, the letter from the primary mentor should clearly describe their roles in the applicant's training. **IMPORTANT: It is the applicant's responsibility to provide these instructions to the mentor(s) for the proposed fellowship.**
- i. **Other proposal attachments (optional):** Examples of additional optional attachments (if applicable) include letters of support from collaborators or consultants, or documentation related to approval for the use of vertebrate animals or human subjects. (See Policies and Procedures; IRB/IACUC documentation will be required prior to funding if selected for an award).

13. Validate: Click the VALIDATE button to check for any missing REQUIRED information or files. All missing required information will be listed on the screen. Please correct any missing information before submitting your application.

14. Submit: You will be unable to submit if you have not provided all the required information. Any missing information will be listed on the screen. If your submission is successful, you will receive a confirmation message on the screen and a confirmation will be sent to the applicant.

Category lists and definitions, for fields to be completed on the Title Page.

| 1. Research Type | Definitions |
|-------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Basic | Basic research is the systematic study of the fundamental aspects of phenomena and of observable facts without specific development of processes, products or clinical applications. Projects typically include studies of the mechanisms of normal or disease related processes at the molecular, cellular, systems or organ level. |
| Translational | Translational research is the process of developing ideas, insights, and discoveries generated through basic scientific inquiry for the treatment or prevention of human disease. |
| Clinical | Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research typically includes therapeutic interventions and applications of new technologies, clinical trials, epidemiologic and behavioral studies, outcomes research and health services research. |

| 2. Research Classification | Definitions |
|-----------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Etiology | Research included in this category aims to identify the causes or origins of epilepsy - genetic, infectious, metabolic, environmental, or other factors, and the interactions between these factors |
| Mechanism of Disease | Research included in this category looks at the biology of how epilepsy/seizures starts and progresses as well as normal biology relevant to these processes |
| Prevention | Research included in this category looks at identifying interventions which reduce the risk of developing epilepsy or its co-occurring conditions by reducing exposure to risk factors and/or increasing protective factors. Interventions may target lifestyle or may involve drugs or vaccines. |
| Detection/Diagnosis/Prognosis | Research included in this category focuses on identifying and testing biomarkers, technology methods or predictive models that are helpful in detecting and/or diagnosing as well as predicting the outcome or chance of recurrence |
| Treatment | Research included in this category focuses on identifying and testing treatments, such as novel therapeutics, devices or other interventions. |
| Outcomes | Research included in this category includes a broad range of areas: surveillance and epidemiology; ethics, education and communication approaches for health care professionals, patients and families, and community members; patient care and health care services research; effectiveness research and phase 4 trials |
| Model Systems | Research included in this category looks at the development of new animal models, cell cultures and computer simulations and their application to other studies across the spectrum of epilepsy research |

3. Epilepsy Type

- a. ADEAF - Autosomal Dominant Epilepsy with Auditory Features
- b. ADNLE - Autosomal-Dominant Nocturnal Frontal Lobe Epilepsy
- c. Alpers Syndrome
- d. Angelman Syndrome
- e. BECTS - Benign Epilepsy with Centrotemporal Spikes
- f. Behavioral, psychosocial, or cognitive comorbidities associated with epilepsy
- g. BFNE - Benign Familial Neonatal Epilepsy
- h. CAE - Childhood Absence Epilepsy
- i. Catamenial Seizures
- j. Childhood Epilepsy
- k. Dravet Syndrome
- l. Early Life Seizures
- m. EME - Early Myoclonic Encephalopathy
- n. Encephalitis Acquired Epilepsy
- o. Epilepsy/Seizures associated with other disorders (like Alzheimer's, Autism, Fragile X, Malaria, ...)
- p. Epilepsy/Seizures in pregnant women
- q. Epilepsy/Seizures in the elderly
- r. Epileptic Encephalopathies
- s. Febrile Seizures
- t. Focal Epilepsy
- u. GEFS+ - Genetic Epilepsy with Febrile Seizures plus
- v. Genetic Epilepsy
- w. Hemiconvulsion–Hemiplegia–Epilepsy
- x. Hypothalamic Hamartoma with Gelastic Seizures
- y. IS - Infantile Spasms
- z. JAE - Juvenile Absence Epilepsy
- aa. JME - Juvenile Myoclonic Epilepsy
- bb. KCNQ2 Encephalopathy
- cc. Lafora Disease
- dd. LGS - Lennox -Gastaut Syndrome
- ee. LKS - Landau-Kleffner syndrome
- ff. Malformations of Cortical Development
- gg. Neonatal Seizures
- hh. Neurocysticercosis
- ii. Nodding Syndrome
- jj. Non-Epileptic Seizures
- kk. Ohtahara Syndrome
- ll. PCDH19 Epilepsy
- mm. PME - Progressive Myoclonus Epilepsies
- nn. PMSE - Polyhydramnios, Megalencephaly and Symptomatic Epilepsy Syndrome
- oo. PTE - Post Traumatic Epilepsy
- pp. Rasmussen Syndrome
- qq. Reflex Epilepsies
- rr. Seizures
- ss. Status Epilepticus
- tt. Sturge-Weber Syndrome
- uu. Succinic Semialdehyde Dehydrogenase Deficiency
- vv. SUDEP
- ww. TLE - Temporal Lobe Epilepsy
- xx. TSC - Tuberous Sclerosis Complex
- yy. West Syndrome
- zz. Epilepsy – not otherwise specified