Epilepsy Foundation Clinical Research 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 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 attend the Pipeline or AEDD meeting, attend the AES annual meeting and participate in the AES 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 Apprenticeship awards $25,000 for one year for salary plus $10,000/year towards classwork and travel to appropriate meetings. Complimentary registration to the AES annual meeting will be included. The award program is funded the Epilepsy Foundation and administered by AES.

APPLICATION DEADLINES AND AWARD DATES

- September 1, 2017: Application submission opens through proposalCENTRAL
- October 5, 2017: Letters of Intent due
- November 30, 2017: Applicants invited to submit full proposals
- January 31, 2018: Full proposals due
- May 14, 2018: Award notifications sent out
- July 1, 2018: Earliest start date

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 are particularly encouraged from women, members of minority groups, and people with disabilities.

SELECTION
Applications are evaluated based upon the quality of the proposed research training program; the applicant’s qualifications; the mentor’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.

Evaluation criteria include:

**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 of high quality for the scientific and professional development of the candidate?

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

SUPPORT
Successful applicants receive funding from the Epilepsy Foundation in the amount of $25,000 for one year for salary plus $10,000/year towards classwork and travel to appropriate meetings. They will also receive complimentary registration for the AES annual meeting and one year of complimentary AES membership.

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. If the research plan has already been approved or exempted by an IRB, because the grantee’s proposed workplan is encompassed by an existing research project grant, then this documentation will be sufficient provided that the IRB concludes that the participation of the grantee does not lead to a substantial modification of the research plan.

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. If the research plan has already been approved or exempted by an IACUC, because the grantee’s proposed workplan is encompassed by an existing research project grant, then this documentation will
be sufficient provided that the IACUC concludes that the participation of the grantee does not lead to a substantial modification of the research plan.

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, 2017**

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/](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 are listed below. They should 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, 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. **Enter the title of your proposal** (max 80 characters)
   b. **Research Type (basic, translational, or clinical).** Definitions for the categories are available at the end of these instructions (p6). Multiple categories are often relevant to an individual project. Please
select one category as the primary type of research that best fits your proposal and then indicate in the boxes below what percentage of your research falls within each category.

c. **Categorize your research project by the type of epilepsy or seizure under investigation.** While multiple categories may be relevant to an individual project, please select a maximum of two choices (one primary and one secondary) that best fit your proposal.

d. **Categorize your research based on its classification.** Definitions for the research classifications are available at the end of these instructions (p9). While multiple categories may be relevant to an individual project, please select up to two choices (one primary and one secondary) that best fit your proposal.

e. **Funding Partners.** In addition to AES and the Epilepsy Foundation, one or more mission-aligned organizations from the Epilepsy Leadership Council may consider providing full or partial support for proposals in targeted research areas. Please confirm whether we may share your application with relevant non-profit funding partners for consideration.

f. **Other sources of funding.** Please indicate whether the proposed work overlaps with that covered by another source of funding, either for the applicant or mentor. List other funding sources accordingly.

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.**
8. **Demographic Information**: All demographic information is voluntary and pre-loaded from the applicant’s PROFESSIONAL PROFILE.

   a. **ORCID ID**: All applicants are encouraged but not required to connect your application to your ORCID ID (available through the Personal Data for Applications within your Professional Profile). The ORCID ID is a persistent digital identifier that distinguishes you from other researchers, helping to ensure that your professional activities over time are linked to your identity.

   b. EF and AES are committed to supporting a strong, diverse, and inclusive research workforce. If you choose to provide information such as gender, race and ethnicity, or disability status, it will be used to help understand our granting programs through analysis of de-identified aggregated data. Such demographic information will not be available to the reviewers of your research proposal.

**FULL PROPOSALS: due by January 31, 2018**

Applicants will be notified by November 30 on whether their Letter of Intent (LOI) is approved. Only applicants with an approved LOI are eligible to submit a full proposal. Instructions on submitting the full proposals will be made available in updated application guidelines before November 30.

**CATEGORY LISTS & DEFINITIONS, FOR FIELDS COMPLETED ON THE TITLE PAGE**

<table>
<thead>
<tr>
<th>Research Type</th>
<th>Definitions</th>
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<tbody>
<tr>
<td><strong>Basic</strong></td>
<td>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.</td>
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<tr>
<td><strong>Translational</strong></td>
<td>Translational research is defined here as research to actively develop and/or refine specific processes, products, clinical applications, and implementation practices that can ultimately be used by patients or healthcare providers.</td>
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<tr>
<td><strong>Clinical</strong></td>
<td>Patient-oriented research, possibly with basic or translational goals, that is conducted with human subjects or on material of human origin (e.g. 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 but cannot be linked to a living individual. Patient-oriented research can encompass physical or behavioral aspects of epilepsy, therapeutic interventions, applications of new technologies, clinical trials, epidemiologic studies, outcomes research, public health, and health services research.</td>
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**Epilepsy or Seizure Type.** This listing has been revised from previous years in response to the 2017 Classification of Seizures Types by ILAE.

- Seizures – Focal or localization-related
- Seizures – Generalized
- Seizures – combined generalized & focal
- Seizures – unknown type
- Seizures – catamenial
- Seizures – early life
- Seizures – febrile
- Seizures – neonatal
• Seizures – Status Epilepticus
• Seizures – other
• Seizures in childhood
• Seizures in pregnant women
• Seizures in geriatric populations
• Seizures in other disorders (e.g. Alzheimer’s, Autism, alcohol abuse, addiction, renal failure, hepatic encephalopathy, Fragile X)
• Epilepsy – Autosomal Dominant Epilepsy w Auditory Features (ADEAF)
• Epilepsy – Autosomal-Dominant Nocturnal Frontal Lobe Epilepsy (ADNFLE)
• Epilepsy – Childhood Absence Epilepsy (CAE)
• Epilepsy – Childhood Epilepsy with Centrottemporal Spikes (formerly BECTS)
• Epilepsy – Dravet Syndrome
• Epilepsy – Early Myoclonic Encephalopathy (EME)
• Epilepsy – Epileptic Encephalopathies
• Epilepsy – Genetic Epilepsy with Febrile Seizures plus (GEFS+)
• Epilepsy – Hemiconvulsion–Hemiplegia–Epilepsy
• Epilepsy – Infantile Spasms (IS)
• Epilepsy – Juvenile Absence Epilepsy (JAE)
• Epilepsy – Juvenile Myoclonic Epilepsy (JME)
• Epilepsy – KCNQ2 Encephalopathy
• Epilepsy – Landau-Kleffner syndrome (LKS)
• Epilepsy – Lennox-Gastaut Syndrome (LGS)
• Epilepsy – Ohtahara Syndrome
• Epilepsy – Polyhydramnios, Megalencephaly and Symptomatic Epilepsy Structural Syndrome (PMSE)
• Epilepsy – Progressive Myoclonus Epilepsies (PME)
• Epilepsy – Reflex Epilepsies
• Epilepsy – Self-limited neonatal seizures or familial neonatal epilepsy (formerly BFNE)
• Epilepsy – Temporal Lobe Epilepsy (TLE)
• Epilepsy – Unknown or other
• Epilepsy – West Syndrome
• Etiology – celiac disease, epilepsy, and cerebral calcification syndrome
• Etiology – Encephalitis
• Etiology – genetic
• Etiology –Alpers Syndrome
• Etiology –Angelman Syndrome
• Etiology –Lafora disease
• Etiology –other
• Etiology –PCDH19 Epilepsy
• Etiology –SCN8A
• Etiology – immune
• Etiology –anti- AMPA receptor antibody
• Etiology –anti- LGI antibody
• Etiology –antibody-mediated
• Etiology –anti-GABA-B receptor antibody
• Etiology –anti-GAD65 antibody
• Etiology –anti-NMDA receptor encephalitis
• Etiology –Rasmussen encephalitis
• Etiology –voltage-gated potassium channel antibody
• Etiology – infectious
• Etiology –Bacterial meningitis / meningoencephalitis
• Etiology –Cerebral malaria
• Etiology –cerebral toxoplasmosis
• Etiology –CMV
• Etiology –HIV
• Etiology –Neurocysticercosis
• Etiology –Nodding Syndrome
• Etiology –other/unknown
• Etiology –Tuberculosis
• Etiology – metabolic
• Etiology –Biotinidase and holocarboxylase synthase deficiency
• Etiology –central folate deficiency
• Etiology –creatine disorders
• Etiology – folinic acid responsive seizures
• Etiology –glucose transporter 1 (GLUT1) deficiency
• Etiology –mitochondrial disorders
• Etiology –peroxisomal disorders
• Etiology –pyridoxine dependent epilepsy/PNPO deficiency
• Etiology –Succinic Semialdehyde Dehydrogenase Deficiency
• Etiology – steroid responsive encephalopathy with autoimmune thyroiditis (Hashimoto disease)
• Etiology – structural
• Etiology –Hypothalamic Hamartoma with Gelastic Seizures
• Etiology –Malformations of Cortical Development
• Etiology – other/unknown
• Etiology – Sturge-Weber Syndrome
• Etiology – Tuberous Sclerosis Syndrome
• Etiology – Post-traumatic epilepsy (PTE)
• Etiology – hypoxia-ischemia
• Comorbidity or consequence
• Comorbidity or consequence – behavioral, psychosocial, or cognitive co-occurring condition
• Comorbidity or consequence – SUDEP
• Epilepsy imitator – headache
• Epilepsy imitator – movement disorders
• Epilepsy imitator – Non-Epileptic Events
• Epilepsy imitator – paroxysmal non-epileptic event
<table>
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<tr>
<td>Etiology</td>
<td>Research included in this category aims to identify the causes or origins of epilepsy and its co-occurring conditions- genetic, infectious, metabolic, environmental, or other factors, and the interactions between these factors</td>
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<tr>
<td>Mechanism of Disease</td>
<td>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. Research may also look at the biology of co-occurring conditions as they relate to epilepsy patients, such as depression, anxiety, autism, Alzheimer’s, and traumatic brain injury.</td>
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<td>Prevention</td>
<td>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 behavioral changes and may involve drugs, devices, or vaccines.</td>
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<tr>
<td>Detection/Diagnosis/Prognosis</td>
<td>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 of seizures and/or co-occurring conditions</td>
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<tr>
<td>Treatment Development or Evaluation</td>
<td>Research included in this category focuses on developing and testing treatments, such as novel therapeutics, devices or other interventions to target seizures and co-occurring conditions.</td>
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<tr>
<td>Outcomes</td>
<td>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; self-management interventions, effectiveness research and phase 4 trials</td>
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<tr>
<td>Model Systems</td>
<td>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.</td>
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<tr>
<td>New Technology and Methodology</td>
<td>Research included in this category is primarily focused on developing new technologies and methodologies for use in epilepsy research, clinical care, or self-management.</td>
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