REQUEST FOR PROPOSALS

CLINICAL RESEARCH TRAINING APPRENTICESHIP

PROVIDING TRAINING AND SUPPORT TO THE NEXT GENERATION OF CLINICAL TRIALISTS

OVERVIEW

The Epilepsy Foundation (EF) seeks to advance the careers of clinical professionals committed to the care of individuals with epilepsy and improving their lives through research. We are therefore funding a 1-year opportunity for trainees to learn about clinical research first-hand, **by becoming involved with an ongoing rigorous research endeavor**. We recognize that there is limited feasibility in an epilepsy trainee getting a new study off the ground and completed within the course of a year due to administrative issues from IRB approvals to recruitment of participants. However, we believe that it is critical for clinical trainees to be able to conduct research and have exposure to clinical investigation for their professional development. We therefore are providing an opportunity for trainees to perform research under the umbrella of an ongoing research study, and to be mentored by one of the senior investigators on the study team who will provide didactic training and support during the course of the award. Research studies would fall under the T1-T4 types of clinical research as defined by new Institute of Medicine and Clinical Translational Study Awards (please look at our FAQs for additional information regarding the types of research supported with this award.) The goal is for the trainee to perform original research but also to learn research methodology from experts. This apprenticeship program is a way for awardees to gain exposure to ongoing clinical investigation as well as develop scientific skills. They may also be able to obtain preliminary data for future grant submissions.

The Clinical Research Training Apprenticeship awards $35,000 for one-year, with a minimum of 25% protected time. These funds can go towards research expenses, coursework/training or to offset salary support up to 25% of the applicant's salary and fringe since that's the required percent effort. The applicant can defer the award for up to a year upon acceptance.

The Epilepsy Foundation will fund the fellowships and manage the review of the proposals. The American Epilepsy Society will provide administration of the award and contribute one year of membership and registration to the AES Annual Meeting, where the awardee will be included in mentorship and professional development opportunities alongside a cohort of early career epilepsy scientists.

Contents

APPLICANT ELIGIBILITY

To apply for this grant, applicants must either be:

- A neurology resident applying to an epilepsy fellowship at a NAEC level 3 or 4 epilepsy center in the United States, or
- an epilepsy fellow (or instructor equivalent) currently at a NAEC level 3 or 4 epilepsy center in the United States.

If awarded, the applicant can defer acceptance of the award for up to one year, if they have already accepted an Accreditation Council for Graduate Medical Education (ACGME) fellowship slot. The applicant must be able to demonstrate that they will have at least 25% protected time that they can apply towards the research project during the one-year term of the award.

KEY CONSIDERATIONS

The research project description must contain the research training plan and the mentorship plan. In addition, the application must upload letters of support from the fellowship training director, the principal investigator of the research endeavor and mentor.

RESEARCH TRAINING PLAN

The research training plan should not exceed 4 pages. Critical to the research training proposal is that an ongoing funded clinical research endeavor is being leveraged. This research endeavor can be single-center or multi-center, and can be funded by NIH, a foundation, industry or another source. In this section, the applicant should outline the research question that they will be exploring within the context of the ongoing clinical research, their role in conducting this research, what amount of protected time the applicant has to do this work during the course of the year (minimum required: 25%), and how this work will contribute to their professional development.

Please note that the research to be conducted by the applicant must be asking a different question, timeline or population from the primary research question addressed in the ongoing clinical research endeavor.

Examples of research studies could be (but are not limited to):

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- New analysis of a patient subset within the ongoing clinical research
- Determination of study recruitment effectiveness and ways to improve the clinical trial design
- Incorporating a wearables device component to the ongoing study
- Conducting a seizure frequency/cycles/triggers analysis on collected data
- Including an additional quality of life measure,
- Adding a healthcare utilization study component

MENTORSHIP PLAN

The application must also identify a mentor who will work with the applicant to create an individualized training program that could consist of both didactic training and a supervised research experience designed to develop the necessary knowledge and skills in the chosen area of research and foster the career goals of the candidate. The mentorship plan should not exceed 2 pages.

The mentorship plan must include opportunities for the Clinical Research Apprenticeship awardee for professional enrichment and research training beyond the research project, such as completion of the EPIPORT online clinical research training program. In addition, they should attend the Epilepsy Foundation Pipeline Conference or the Epilepsy Study Consortium Anti-Epileptic Drug and Device Trials meeting (the Epilepsy Foundation will waive the registration fees for these two meetings) and the attend the annual meeting of the American Epilepsy Society to participate in mentorship and professional development programs (the AES will waive the registration fee).

Note that if the mentor identified is not the primary study PI, a letter of support will be necessary from the study PI or sponsor to ensure that they are aware of the application and support this proposal.

LETTERS OF SUPPORT

For the application to be reviewed, the applicant will need to also include the following letters of support with their application:

- Letter of support from the fellowship training director that the fellowship provides at least 25% elective/protected time for the fellow to complete the work outlined.
- Letter of support from the primary study principal investigator or primary sponsor that they are aware of this proposal and support this application.
- Letter of support from the identified mentor (who may also be the primary study principal investigator) approving of the mentorship plan as outlined.

Note that if the letter of support from the primary study principal investigator and mentor are the same, those letters of support may be combined. However, the combined letter of support should clearly address both support for the research proposal and the mentorship plan.

APPLICATION INSTRUCTIONS

Applications include the following steps and components. Please go to ProposalCentral to learn more.

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1. **Title Page:** Enter the project title. (Do not exceed 75 characters)

2. **Download Templates and Instructions:** Download RFP and templates.

3. **Enable Other Users to Access this Proposal:** Allow others (e.g., institutional administrators or collaborators) to view, edit, or submit your proposal.

4. **Applicant/PI:** Key information about the applicant PI.

5. **Institution & Contacts:** Key information about the Applicant/PI's institution, including name and email address of mentor, the signing official who, in addition to the PI, will be contacted if the award is selected for funding, and financial officer (for where the checks should get sent to).

6. **Lay Summary & Abstract:** Provide a lay audience friendly abstract and a technical abstract (1,500 characters maximum each) and key words. Please note: the lay abstract will become public if the award is selected for funding; therefore, it should not contain any proprietary information.

7. **Budget Period Detail:** The Clinical Research Training Apprenticeship awards $35,000 for one-year, with a minimum of 25% protected time. These funds can go towards research expenses, coursework/training or to offset salary support up to 25% of the applicant's salary and fringe since that's the required percent effort. Outline how the $35,000 will be spent.

8. **Budget Summary & Justification:** This section will summarize the amounts placed in section 7: Budget Period Detail. Provide a brief justification of budget, highlighting how this will ensure the projects success.

9. **Organizational Assurances:** Clarify compliance with Human Subjects and Vertebrate Animals. We recognize that some of the studies proposed for human subjects may require an amendment to the existing IRB submission, and that this amendment may not have gone through review at time of application. We also recognize that these studies will be very unlikely to require vertebrate animals. Therefore, you may select either approved/pending/exempt/not applicable as appropriate for these sections.

10. **Upload Attachments:** Upload the following:

    a. *Biosketch for applicant and mentor*: Applicants and mentors may use the NIH biosketch format in the download templates section
    b. *Other Support for applicant and mentor:* Applicant and mentor must list their current & pending research support using the template provided in proposalCENTRAL, which includes a statement of overlap between this proposed project and the other support. Any overlap of current or pending support with the Epilepsy Foundation proposal must be described and explained.
    c. *Project description:* Must be formatted in Arial 11 point or Times New Roman 12 point font with no less than ½ inch margins. 6 pages maximum, inclusive of both the research training plan (4 pages) and the mentorship plan (2 pages).

d. *IRB award letter:* We recognize that some of the studies proposed may require an amendment to the existing IRB submission, and that this amendment may not have gone through review at time of application. However, we will need the existing IRB award letter to which the project will be amended in the application submission. If the application is awarded (and it is applicable), we will also need the amendment IRB number prior to funding award.

e. **Letter of support from the fellowship training director** that the fellowship provides at least 25% elective/protected time for the fellow to complete the work outlined.

f. **Letter of support from the study principal investigator or primary sponsor** that they are aware of the apprentice's study proposal and support this application.

g. **Letter of support from the identified mentor** (who may also be the primary study principal investigator) approving of the mentorship plan as outlined.

11. **Signature pages:** Print the signature page, which must be signed by the PI and the institution's signing official, and uploaded as part of the application package.

12. **Validate:** Check for any missing required information.

13. **Submit:** Please note that no proposals will be accepted past the deadline. Technical support for the on-line application system is not available after 5:00 PM Eastern Time, Monday through Friday.

TIMELINE

- ~~**Monday, September 30, 2019:**~~ **Deadline extended to October 15, 2019**: Full-length proposals are due by 5:00 PM Eastern Time
- **January 6, 2020:** Awardees notified (Epilepsy Foundation may adjust date without notice to applicants)
- **July 6, 2020:** Projects commence. Awardees may defer their award up to 1 year.

REVIEW MECHANISM

All proposals will undergo rigorous peer review by members of the Epilepsy Foundation Professional Advisory Board and a reviewer nominated by the American Epilepsy Society. The reviewers will be assessing the research training plan, the mentorship plan, and the environment within which the applicant will be conducting their research. Below is a list of questions that reviewers will be asked to consider.

Questions the reviewers will consider:

RESEARCH TRAINING PLAN

- Does the research plan leverage existing clinical research infrastructure?
- Will the training plan help the applicant develop research skills related to the design, conduct, and analysis of clinical research?
- Is the applicant's role in the project clearly defined?
- Is there sufficient protected time for the applicant to complete the research proposed?
- Is there a specific plan for applicant to attend national scientific meetings (especially the annual meeting of the American Epilepsy Society and either the AEDD or Pipeline Conference), the

MENTORSHIP PLAN

- Are the mentor's research qualifications (including successful completion of a clinical research endeavor (whether from NIH or industry) appropriate for the proposed fellowship?
- Is the mentor involved in the clinical research endeavor that the applicant will be conducting? If the mentor is not involved in the apprenticed study, is their evidence of support from the study principal Investigator?
- 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?

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?

The Epilepsy Foundation will provide reviewer evaluations to applicants through proposalCENTRAL.

AWARD ADMINISTRATION

Final decision for awarding the successful applicants will be taken jointly by the Epilepsy Foundation and the American Epilepsy Society Research & Training Council.

The award will be administered through the American Epilepsy Society (AES), the professional home for epilepsy clinicians and scientists. The award will fall under the early career development awards system that AES conducts.

The awardee will receive $35,000, funded by the Epilepsy Foundation, for use as outlined above. In addition, the American Epilepsy Society will provide one year of complimentary membership and complimentary registration to the AES Annual Meeting, where the awardee will be included in mentorship and professional development opportunities alongside a cohort of early career epilepsy scientists.

FREQUENTLY ASKED QUESTIONS

ELIGIBILITY AND TIMELINE

Q: Must an applicant already be a clinical fellow at an epilepsy level 3 or 4 center?

A: Not necessarily. Applicants can also be adult or pediatric neurology residents in their final two (2) years of training who are applying or have been accepted to an epilepsy or clinical neurophysiology fellowship at an NAEC level 3 or 4 center. Applicants may also be an instructor equivalent of a fellow to be eligible.

Q: What amount of time needs to be protected to receive the funds?
A: We require a minimum of 25% protected time during the course of a year for the research study. The research study does not need to require more than 25% effort over a year to complete.

Q: Could I defer if awarded?
A: Yes, awarded applicants would have the option to defer their award for a year, if this works better with the requirements of their fellowship program.

Q: Does the mentor need to be the main study principal investigator?
A: No. However, part of the review criteria will be to assess how closely the identified mentor is to the large research endeavor that the apprenticed study would leverage.

APPLICATION COMPONENTS

Q: How are full proposals submitted?
A: All proposals must be submitted electronically via proposalCENTRAL. The signature page should be signed and a scanned PDF copy be uploaded as part of the application in proposalCENTRAL.   Hard copies will not be accepted.

Q: What is the total amount of the award? And how can the funds be used?
 A: The Clinical Research Training Apprenticeship awards $35,000 towards research expenses and/or salary support. The expenses could go towards anything in the research project such as part of a clinical coordinator's salary, reagents. For salary support, grant funds may only be used to offset up to 25% of the applicant's salary and fringe. Also, up to $10,000 of the award could also be applied towards classwork and travel to appropriate meetings.

Q: What type of large research endeavor would qualify for support?
A: We are focusing on T1-T4 studies as defined by the new Institute of Medicine and clinical translation science awards (CTSA) definitions. Therefore, not included would be T0 research which encompasses basic biomedical research, including preclinical and animal studies. However, we would consider the following:

- T1 Research: translation to humans, including proof of concept studies, Phase 1 clinical trials, and focus on new methods of diagnosis, treatment, and prevention in highly-controlled settings;
- T2 Research: translation to patients, including Phase 2 and 3 clinical trials, and controlled studies leading to clinical application and evidence-based guidelines;
- T3 Research: translation to practice, including comparative effectiveness research, post-marketing studies, clinical outcomes research, as well as health services, and dissemination & implementation research; and
- T4 Research: translation to communities, including population level outcomes research, monitoring of morbidity, mortality, benefits, and risks, and impacts of policy and change.

For additional questions about whether a research endeavor would fit, please contact grants@efa.org.

Q: Is the NIH biosketch CV format acceptable for submission?
 A: Yes, you may use your NIH biosketch when uploading in proposalCENTRAL.