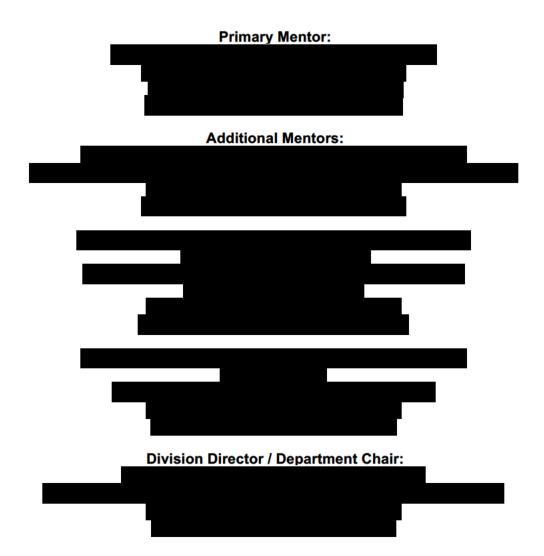
Perspectives of General Pediatricians and Adolescent Medicine Specialists on Sexual and Reproductive Healthcare for Adolescent and Young Adult Women with Epilepsy

PI:

Funding path: Young Investigator Award Program



## **Participation Statement**

If funded, I agree to participate in any conference calls and/or in person grantee meetings.

## **SPECIFIC AIMS:**

Adolescent and young adult (AYA) women with epilepsy have unique and unmet needs for sexual and reproductive healthcare (SRH). They are at risk for adverse health outcomes, including fetal teratogen exposure and drug-drug interactions between antiseizure medications and hormonal contraception leading to poor seizure control and contraceptive failure (1, 2). They also report low rates of discussing contraception with any physician, as well as low levels of knowledge about SRH and their underlying disease (3, 4). The PI's qualitative interviews with child neurologists revealed that neurologists rely on primary care providers and adolescent medicine specialists for SRH for these patients, yet are concerned that these providers are not aware of important epilepsy-specific SRH issues (5). The knowledge, attitudes, and practices of primary care providers and adolescent medicine specialists regarding SRH for AYA women with epilepsy are unknown. Characterizing these domains is critical for understanding gaps in SRH for AYA women with epilepsy and designing interventions to improve care for this population.

We propose the first survey of primary care providers and adolescent medicine specialists to characterize their knowledge, attitudes, and practices regarding SRH care for AYA women with epilepsy. We hypothesize that these providers believe that SRH is important for this population, yet have disease-specific knowledge deficits regarding their SRH. We expect that these providers can identify specific barriers and facilitators to high-quality SRH for this population. Our long-term goal is to use the data from this survey to develop interventions to improve the quality of SRH for AYA women with epilepsy, including patient education, provider training, and health systems initiatives. We are positioned to undertake this research because of our preliminary qualitative data and our team's multidisciplinary expertise in neurology, general pediatrics, and adolescent medicine.

**Aim 1** will be to identify current knowledge, attitudes, and practices of pediatric primary care and adolescent medicine providers regarding SRH for AYA women with epilepsy. We will conduct a web-based survey with pediatric primary care and adolescent medicine providers regarding their experiences related to SRH with AYA women with epilepsy. We will characterize strengths and areas for intervention in current practice. The outcome will be data that will be used as a foundation for future health services interventions to improve SRH for AYA women with epilepsy among general pediatricians, adolescent medicine specialists, and neurologists.

#### **BACKGROUND:**

Adolescent and young adult (AYA) women with epilepsy have unique needs for sexual and reproductive healthcare (SRH). Unintended pregnancy in women with epilepsy is associated with an elevated risk of spontaneous fetal loss (6). Commonly-used antiseizure medications, such as valproic acid and topiramate, are teratogens (1). CYP450 enzyme-inducing antiseizure medications reduce the effectiveness of oral contraception, and oral contraception reduces lamotrigine levels (1, 2). Though pregnancy planning is considered particularly important for women with epilepsy, adult women with epilepsy have reported that over half of their pregnancies are unintended (7, 8).

Little is known about the SRH experiences of AYA women with epilepsy, but current literature suggests unmet needs. In a survey of AYA women with epilepsy regarding SRH experiences, a minority reported ever discussing contraception with any physician, and a majority reported wanting more information (3). AYA women with epilepsy also have poor knowledge regarding SRH and their underlying disease, answering less than one-fifth of questions correctly in a recent knowledge assessment (4).

In preliminary qualitative interviews with pediatric neurologists about SRH needs of AYA women with epilepsy (5), they reported that strong working relationships with primary care pediatricians and adolescent medicine specialists can be facilitators of high-quality reproductive healthcare for AYA women with epilepsy. In addition, they reported often relying on primary care pediatricians and adolescent medicine specialists for addressing their patients' SRH needs,

particularly in-depth contraceptive counseling and prescription of contraceptive methods. However, some also reported concerns about these providers' ability to accurately address the epilepsy-specific SRH needs of this population and cited misinformation from other specialties as a potential barrier to optimal care for AYA women with epilepsy.

### **SIGNIFICANCE**

There are no previous studies regarding the knowledge, attitudes, and practices of pediatric primary care and adolescent medicine providers regarding SRH for AYA women with epilepsy. Our preliminary data from qualitative interviews with pediatric neurologists suggests that primary care providers and adolescent medicine specialists are a strong asset in ensuring high-quality SRH for AYA women with epilepsy. However, interview participants also discussed that primary care pediatricians and adolescent medicine specialists can also at times be a source of misinformation about SRH for their patients, particularly regarding epilepsy-specific SRH needs. This survey will allow us to characterize strengths and areas for improvement in current practice. Survey results will inform initiatives to improve provision of SRH for AYA women with epilepsy, including patient education, provider training, and health systems interventions. By promoting provision of SRH, AYA women with epilepsy will be at less risk for adverse health outcomes including unplanned pregnancies, drug interactions leading to poor seizure control, and potential fetal teratogen exposure. We believe that this project fits the APA's mission of promoting improvement science, highest-quality patient-centered care, and multidisciplinary collaboration.

#### **METHODS**

Study design/population: Pediatric primary care providers and adolescent medicine specialists who are members of the chapter of the American Academy of Pediatrics (n~2200) will be invited to complete a computerized online survey. We believe that recruiting participants locally will lead to the most favorable response rate for the survey and yield a generalizable sample of pediatric primary care and adolescent medicine providers. Study procedures: Participants will answer questions regarding demographic information and SRH experience with AYA women with epilepsy. Because caring for AYA women with epilepsy may be uncommon for primary care and adolescent medicine providers, we will also use case vignettes to further address knowledge, attitudes, and practices. Specific question topics will include the overall importance of SRH care to AYA women with epilepsy; knowledge assessment of specific SRH topics; attitudes about pediatric neurologists and epileptologists; and barriers and facilitators to SRH care. Content of this survey will be dictated by qualitative analysis of interviews conducted by the principal investigator (5). Themes and subthemes identified from the preliminary qualitative work will inform questionnaire item content and structure. Face and content validity will be further refined with review by content experts, pilot testing and cognitive interviewing. The survey will be brief (~5-10 minutes), anonymous, and conducted via the secure Qualtrics<sup>™</sup> platform. A sample size of 399 pediatricians would achieve 80% power to detect a difference of 0.07 using a two-sided Z-test to estimate the standard deviation with a significance level of 0.05. We assume the population proportion for a dichotomous response under the null hypothesis is 0.5. As an incentive, five Apple Watches will be available by chance drawing to survey participants who provide their contact information on a separate online form unconnected to survey responses.

### **TIMELINE**

The project will be completed in one year. The survey will be developed over four months, including one month for an initial draft and three months for redrafting based on validity assessment. The survey will be distributed over a period of three months. Data analysis and preparation of the results will occur during the remaining five months of the year.

### References

- (1) Stephen L, Harden C, Tomson T, Brodie M. Management of epilepsy in women. *Lancet Neurology*. 2019; 18: 481-491.
- (2) Espinera AR et al. Counseling by epileptologists affects contraceptive choices of women with epilepsy. *Epilepsy Behav.* 2016; 65: 1-6.
- (3) Manski R, Dennis A. A mixed-methods exploration of the contraceptive experiences of female teens with epilepsy. *Seizure*. 2014; 23: 629-635.
- (4) Agarwal R, Patel R, Set K, Zidan M, Sivaswamy L. Safety, Awareness, and Familiarity regarding Epilepsy in Teenage Years (SAFETY): understanding the adolescents' perspective about their disease. *Epilepsy Behav.* 2014; 41: 114-118.
- (5) Kirkpatrick L, Collins A, Sogawa Y, Kazmerski T. Pediatric neurologists and epileptologists' perspectives on sexual and reproductive healthcare for adolescent and young adult women with epilepsy. Manuscript in progress. 2019.
- (6) Herzog AG, Mandle HB, MacEachern DB. Association of unintended pregnancy with spontaneous fetal loss in women with epilepsy: findings of the Epilepsy Birth Control Registry. *JAMA Neurol.* 2019; 76: 50-55.
- (7) Herzog AG et al. Predictors of unintended pregnancy in women with epilepsy. *Neurology*. 2017; 88: 728-733.
- (8) Johnson EL, Burke AE, Wang A, Pennell PB. Unintended pregnancy, prenatal care, newborn outcomes and breastfeeding in women with epilepsy. *Neurology*. 2018; 91:e1031-1039.

## **BUDGET & BUDGET JUSTIFICATION**

Item	Detail	In-kind (optional)	Amount requested	Total Amount	Justification
		(0)	from APA	7	
Remuneration	Five Apple Watches to be offered by chance drawing to survey participants.  With an estimated 399 participants, cost comes to \$6.30 per participant.	N/A	\$2500	\$2500	Response rates in physician surveys are traditionally low. Offering an incentive such as an Apple Watch may boost physician participation in surveys. One of my mentors, Dr.  previously achieved strong participation in a healthcare provider survey by offering Apple Watches by chance to respondents.
Software, statistical	One 12-month license for STATA.	N/A	\$300	\$300	Statistical software will be needed for data management. STATA is offered at a subscription rate of \$300 per year per license.
Software, survey management	1 license, Qualtrics survey platform.	100% in-kind	\$0	100% in- kind	This survey platform is available in-kind through the University of
Consultants, statistical support	10 hours of statistical support is available inkind through the University of Clinical and Translational Science Institute. If further hours are needed, Dr. PhD is a	100% in-kind	\$0	100% in-kind	We will require statistical support for optimal data analysis. However, this support is available in-kind through the University of as well as Dr. 's Division of General Academic Pediatrics through Dr. PhD.

Supplies	biostatistician in Dr. 's division who will provide support in- kind. Poster production fee	N/A	\$100	\$100	Estimated cost of printing a poster for PAS for presentation of
PAS travel	Travel to PAS 2021	N/A	\$1300	\$1300	results.  Funding will be needed to cover the cost of travel to PAS 2021 for presentation of the results. Travel costs based on estimate for roundtrip airfare between and plus hotel stay.
Research training***	STATA NetCourseNow 101: Introduction to STATA (\$195)  STATA: NetCourseNow 120: Statistical Graphics Using STATA (\$250)  STATA: NetCourseNow 151: Introduction to STATA Programming (\$250)  Online, on- demand, self- paced courses.	N/A	\$695	\$695	The PI will gain needed career skills by completing self-paced, on-demand, online classes to improve her abilities with statistical software.
TOTAL			\$4895	\$4895	

#### **BIOGRAPHICAL SKETCH**

Prov de the fo owng nformat on for the Sen or/key personne and other s gn f cant contr butors. Fo ow this format for each person. **DO NOT EXCEED FIVE PAGES.** 

NAME:	
eRA COMMONS USER NAME (credential, e.g., agency login):	
POSITION TITLE: Resident physician	

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

INSTITUTION AND LOCATION	DEGREE (if applicable)	Start Date MM/YY YY	Completion Date MM/YYYY	FIELD OF STUDY

## A. Personal Statement

I am a PGY-3 Child Neurology resident interested long-term in a career in health services research focused on improving comprehensive care, particularly sexual and reproductive healthcare, for patients with neurologic conditions, especially epilepsy. My interest in sexual and reproductive healthcare is long-standing, beginning with years of professional experience in family planning prior to and during medical school. I have combined this interest with my career interest in pediatric neurology by founding a working group of pediatric subspecialists interested in sexual and reproductive health, conducting a survey of pediatric subspecialists regarding reproductive healthcare for young women prescribed teratogens, and performing qualitative interviews with pediatric neurologists around their SRH practices with young women with epilepsy. My long-term goal is to develop and test interventions to improve comprehensive care including SRH for young women with neurologic conditions particularly epilepsy.

The proposed project is important groundwork for developing such interventions. Our qualitative interviews suggested that, while neurologists are not comfortable performing contraceptive counseling or prescribing contraception to young women with epilepsy, they are also concerned that general pediatricians and adolescent medicine specialists are not sufficiently familiar with epilepsy-specific SRH needs to consistently do so effectively either. The

proposed project aims to better characterize this potential gap in care so that solutions might be developed and tested as the next step.

The proposed project will be essential to my career development, serving as a critical bridge between my preliminary qualitative work and intended future research in health services interventions. Through this project, I will gain needed career skills and experience in survey design, validity assessment, participant recruitment, and statistical analysis. I will additionally develop mentoring relationships with general pediatricians and adolescent medicine specialists that will also prove invaluable in the next intended phase of the project. I believe that I am uniquely positioned to carry out this research due to my rare combined background in family planning and child neurology. I also believe that this project will serve as an initial foundation for a future research career.

## **B. Positions and Honors**



## C. Contributions to Science

### 1. Peer-reviewed publications



2. Scientific posters



5) D. Additional Information: Research Support and/or Scholastic Performance

## **BIOGRAPHICAL SKETCH**

Provide the following information for the Senior/key personne and other significant contributors.

Following information for the Senior/key personne and other significant contributors.

NAME:	_
eRA COMMONS USER NAME (credential, e.g., agency login):	
DOSITION TITLE: Professor of Padiatries	_

POSITION TITLE: Professor of Pediatrics

EDUCATION/TRAINING (Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)

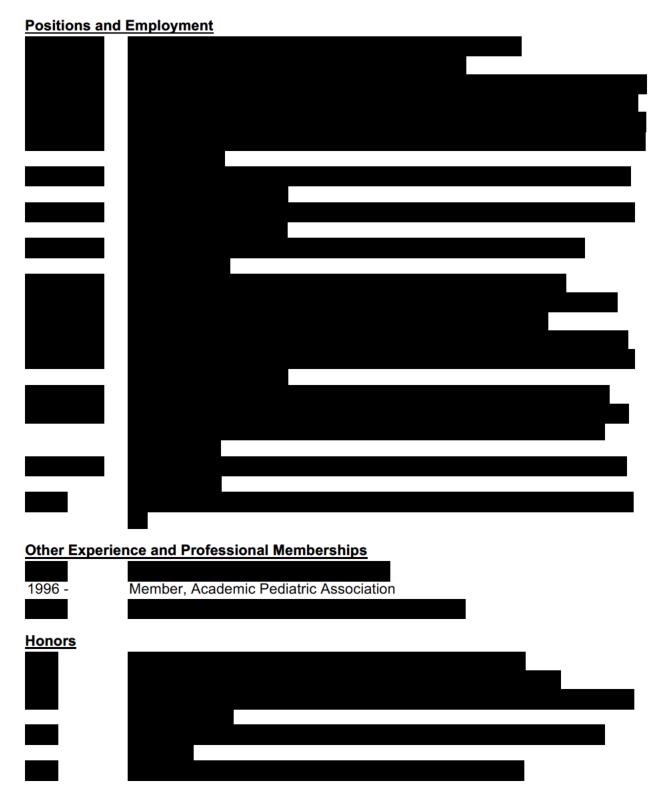
INSTITUTION AND LOCATION	DEGREE	END	FIELD OF STUDY
	(if	DATE	
	applicable)	MM/YYYY	
	I		

### A. Personal Statement

I am a general pediatrician with extensive educational, administrative/leadership and growing clinical research experience. I trained and served in the US Navy for 21 years; 18 as a general pediatrician. After residency, I completed a general academic pediatrics fellowship in 2000 with a Master of Public Health degree with a concentration in health policy and management. My fellowship training included a significant amount of biostatistics, epidemiology and clinical research. After fellowship, I served in educational leadership and management positions in the Navy. I held positions as Associate Residency Program Director and Residency Program Director (4 years each) and the Navy Surgeon General's Specialty Leader for Pediatrics (the chief pediatrician in the Navy) for 3.5 years. After military retirement in 2011, I joined the faculty at University of , Department of Pediatrics, Division of General Academic Pediatrics to focus on clinical research. My scholarly work is in the area of diagnosis and management of common pediatric infectious diseases. I am nationally recognized for my policy work and non-peer-reviewed publications in evidence-based exclusion and return-to-care policies for mildly ill children with infectious diseases in child care and school settings. I've coedited a book, Managing Infectious Diseases in Child Care and Schools, 4th Ed., published by the American Academy of Pediatrics (AAP), that is now is used by almost 3/4 of licensed child care centers in the US, according to a 2016 survey. In this area, I am a sought-after lecturer at national conferences for early childhood educators and pediatricians, have authored numerous online curricula for early childhood educators, and have edited key portions of AAP publications such as the Red Book 2018 and Caring for Our Children: National Health and Safety Performance Standards for Early Care and Education Programs, 3rd Ed. In the past 7 years I have been a co-investigator conducting 7 NIH or CDC-sponsored and 2 private industrysponsored clinical research protocols focused on improving the diagnosis and treatment of

common infectious diseases: acute otitis media, sinusitis, urinary tract infection, influenza, bronchiolitis, and pneumonia.

## **B. Positions and Honors**





## C. Contribution to Science

1. Providing evidence based policies for handling children in early education and child care settings who have common infectious diseases.



2. Defining appropriate diagnosis, antimicrobial treatment and immunization for common pediatric infectious diseases.



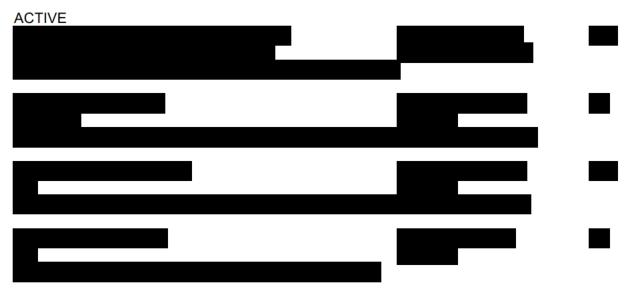
3. Mentorship of students, residents and fellows by helping them address their own clinical research questions.

In my work as a medical educator, I have mentored a large number of learners, some of whom had clinical research questions. I was able to assist them in designing, implementing

and completing manuscripts. These topics are often outside of my central theme of diagnosis and management of common pediatric infectious diseases.



# D. Additional Information: Research Support







Re: Co-Mentor Letter for Dr.

### To the Research Committee Members:

for her Academic Pediatric Association proposal, "Perspectives of general pediatricians and adolescent medicine specialists on sexual and reproductive healthcare for adolescent and young adult women with epilepsy." Dr. has designed an exciting project in which she will survey general pediatricians and adolescent medicine specialists regarding their practices, attitudes, and knowledge about sexual and reproductive healthcare for adolescent and young adult women with epilepsy. She is an excellent candidate for this research award, and this proposal is an essential next step in her career development.

Dr. Soverarching goal is to become an independent investigator examining novel

overarching goal is to become an independent investigator examining novel ways to improve sexual and reproductive healthcare for adolescent and young adult women with neurologic conditions, particularly epilepsy. Dr. has long-standing dedication to sexual and reproductive healthcare for adolescents and young adults since prior to medical school, with professional experience in family planning. She received the prestigious Emerging Activist Award from the National Women's Health Network for her work. She has a rare combination of skills that uniquely position her to pursue a career advancing sexual and reproductive healthcare for adolescent and young adult women with epilepsy.

We have had the opportunity to work closely with Dr. over the past two years during her pediatric residency. She has been exceptionally productive during this time. Her activities during residency illustrate her talent as a junior researcher, who is highly motivated, intelligent, and industrious. She initiated a working group of pediatric subspecialists interested in sexual and reproductive healthcare, leading to an institution-wide survey (for which Dr. served as the PI) on the sexual and reproductive healthcare practices of pediatric subspecialists who prescribe potentially teratogenic medications (abstract in progress). Through this activity, she developed skills in survey development, validity assessment, and dissemination that are crucial for her proposed project. Her prior survey achieved an unusually high 65% response rate – a rarity for provider surveys. The findings of this survey have both institutional and national implications.

Most pertinent to this application, she recently completed qualitative interviews (n=16) with pediatric neurologists and epileptologists on their perspectives on sexual and reproductive healthcare for women with epilepsy (abstract in progress). Through her interviews, she has found that providers defer contraceptive counseling and prescription to general pediatricians and adolescent medicine specialists, yet have concerns that other specialties might not understand the unique sexual and reproductive healthcare needs of these patients. This qualitative data will prove invaluable for developing a quantitative instrument to measure providers' practices, attitudes, knowledge, and experiences in order to understand gaps in care. This formative work has provided Dr. with critical skills and experiences that uniquely position her to undertake the proposed project, as well as prepare her for a future career in patient-oriented research.

In addition, during her rigorous pediatric training, she authored her debut first-author manuscript based on her medical school research on primary care providers' perspectives on prescribing

antidepressant medication to Latinx immigrants in safety-net clinics
For her next manuscript, she investigated the frequency of dystonic reactions due to prochlorperazine versus metoclopramide in children treated for acute headache utilizing nearly 5000 records derived from pharmacy and admission data to determine the incidence for each medication (abstract in progress). She also analyzed whether dystonic reactions were linked to patient age, gender, dosing, and receipt of diphenhydramine. Through this project, she gained important skills in working with large data sets and conducting epidemiological statistical analysis.
She has also been active in quality improvement and educational endeavors. She created an educational handout for women with epilepsy about pregnancy and contraception that is now regularly used by all providers in the Division of Child Neurology through the electronic medical record. She designed an institutional guideline on appropriate neuroimaging for pediatric patients who fall in the hospital. She also initiated a highly successful standardized-patient training for pediatric interns on pregnancy test result disclosure and counseling. To expand this training, she is actively partnering with the pediatric residency program directors and hospital staff to obtain grant funding. Because of her achievements in these areas, we are confident that she will be able to build from the results of the proposed project to design and test interventions to improve comprehensive care for adolescent and young adult women with epilepsy.
Throughout her medical training, Dr. has demonstrated incredible focus, motivation, and dedication. She is intelligent, open to feedback, willing to learn, and highly professional in all her interactions, giving her a firm foundation for a successful research career. Completion of this research will provide Dr. with essential new skills, data, and partnerships that will support her initiation of a research career and ability to compete for investigator funding in the future.
Dr. will serve as her primary mentor for this project. He has extensive experience in general pediatrics patient care and clinical research. His primary research focus is improving the diagnosis and treatment of common pediatric infectious diseases. He has over 8 years of experience designing and conducting numerous NIH clinical trials and private industry studies at . He also has a longstanding interest in improving the management of children with infectious diseases in early education and child care settings. Germane to Dr. 's proposed project, Dr. has successfully mentored several former medical students and residents in various research projects that have been published in respected journals with content areas outside of his research focus. Some of his studies involved survey research
He also has formal training and experience in survey research methodology. Dr. well because he served as her continuity clinic supervisor and clinical mentor during the first two years of her residency. Dr. has >50% protected research time. He plans to formally meet with her in person on a quarterly basis, with ad hoc meetings as needed by phone. Statistical support is requested in Dr. 's budget application, but should additional statistical support be needed, two full-time statisticians are available in Dr. 's division on an in-kind basis.
Drs. will serve as her additional mentors for this project. We have worked with Dr. very effectively in the past on multiple projects and look forward to continuing our mentoring relationship with her. Dr is a highly productive health services researcher with expertise in sexual and reproductive healthcare for adolescent

trainees across several disciplines and subspecialties. Dr. is a recognized expert on pediatric epilepsy syndromes and the Director for Clinical Research in the division of Child Neurology. She has mentored and supervised many pediatric neurology residents in successful research projects. Dr. is the Clinical Director for the Center for Adolescent and Young Adult Health. She has mentored Dr. on her project on providing pregnancy options counseling training to pediatric residents, and worked with Dr. Adolescent Medicine rotation. She has mentored many successful resident research projects.
In summary, Dr. is an ambitious, bright, and committed researcher who is an ideal candidate for the APA's Young Investigator Award. She is an exceptionally driven applicant and it is truly an honor to be able to recommend her to you.
Sincerely,

# Chapter



	August 21, 2019
	Re: Letter of Support for
_	Dear Members of the Research Committee:
	O behalf of the Chapter of the Ame ic n Academy o Pediatrics am writing o expr ss sup ort for Dr p oposal, "Pers ectives of General Pediatricians an do escent ed cine Sp cialist on Sexual a d Reproductiv Healthcare for Adolescent and oung Adult Women ith Epil psy "D is ap lying for the A ademic Pediatric Association' Young Inv sti at r Aw rd. The ai o this project is to exam e t e gap n care th t exists rega din cont acept on for young wome with epile sy This proje t, in ar i ular, se ves as model to ad res p ysic an comm nication acr ss sp ci l ies which is a key fa tor in nhancing qu lity of are and patient safe y.
	The AAP i a state lev 1 rganization o app oximately 2200 pe iat icians who re dedicated to romoti g t e health a d ell-bein of childr n a d h value f pediatr c p ac ice. Dr. 's prop sed pr ject aligns wit our goals and m ss on.
	Dr plan to sur ey general pe iat icians and adolescent me ici e spe ialist ac oss t e t e of . I full sup ort thi project a will p omo e r. 's ur ey o our m mbers to ensu e t at he has access to a stat wide popul ti n of pediatri ian fo her su vey. Throu hout this pro ect, I ill re ai in communica ion ith r. via e ail and via in-per on and/or teleph ne cont ct as need d I w ll a so rem in in communicat on w th Dr. wh wil serv a Dr 'mento fo th proposed project.
	Overall believ tha Dr i ver promisin youn investigator and I support her proposed survey project. I believe she would be a excellen candidate for the APA's Young Investigator Award.
	Sincerely