

### **A. PURPOSE**

The purpose of this grant is to provide support for patient-oriented research such as comparative effectiveness research (CER) and observational cohort studies designed to fill “research gaps” identified by the AAO-HNS/F clinical practice guideline panels, clinical consensus statement panels, and AAO-HNSF clinical and scientific committees. (To view these research gaps listed by subspecialty, go to <http://www.entnet.org/content/clinical-practice-guidelines> and click on “Research Gaps”.) Applicants are strongly encouraged to develop projects which address highlighted gaps (Appendix 1 includes examples of possible projects aimed at identified research gaps that would ideally fit this grant mechanism). Applicants may also choose to develop their own research question(s).

In addition, the AAO-HNSF wishes to support the career development of investigators who have made a commitment to focus their research endeavors on patient-oriented research by helping to develop independent research skills and gain experience in advanced methods and approaches needed to become an independent investigator conducting patient-oriented research.

### **B. ELIGIBILITY**

Otolaryngologists in the United States or Canada are eligible to apply and must be members in good standing of the AAO-HNS. Applicants must have demonstrated potential for excellence in research and teaching and a serious commitment to an academic research career in otolaryngology-head and neck surgery. Priority will be given to junior faculty members who have completed residencies or fellowships within 7 years of the application receipt date. All candidates must be sponsored by the Chairperson of his/her Division or Department. **Applications submitted by ineligible PIs will NOT be reviewed by the CORE Study Section.**

### **C. CONDITIONS**

Projects must have direct or potential clinical significance for patients seen by otolaryngologists-head and neck surgeons. They must be designed so as to yield useful information within the period of award. Projects which address potential research gaps (see examples in Appendix 1) are strongly encouraged. Funds may not be requested to pay any portions of the salaries of the principal investigator or of any support personnel with strictly secretarial or clerical responsibilities. Applications must be accompanied by a letter of support from the applicant’s Department Chair verifying that the applicant will be permitted to devote an appropriate amount of time to the conduct and timely completion of the proposed research project. Applicants must obtain letters of support/understanding from all key personnel on the project.

**Fund Disclosure:** The Academy will withhold up to ten per cent (10%) of the grant until such time that the research project is completed and all requirements have been met, as outlined in section L; Reporting Requirements

### **D. OPPORTUNITIES**

Applicants are strongly encouraged to utilize the Creating Healthcare Excellence through Education and Research (CHEER) network (<http://cheerresearch.org/>) to engage both Academic and Community sites in the project. This added incentive and collaborative opportunity will be made available without additional direct costs for individuals receiving this grant should their study be appropriate in a practice-based research setting. See Appendix 2 for details about how the network can be utilized. Applicants should contact Kris Schulz [kristine.schulz@duke.edu](mailto:kristine.schulz@duke.edu) with any questions about the network and details related to engaging the CHEER sites. If the applicant does plan to utilize the network, those details should be incorporated in the applicants Research Strategy.

### **E. TERMS**

1. **Amount:** \$50,000 maximum total (direct and indirect) costs
2. **Period:** 12 months.

3. **Funding:** One will be awarded annually.
4. **Use of Funds:** Funding may not be used for salary support for the Principal Investigator; however, up to 50% of the total budget may be requested to support non-clerical assistants or other technical personnel. If university policy stipulates that a portion of this modest award must go toward institutional indirect costs, no more than ten percent (10%) of the direct costs may be applied for indirect costs. Equipment and supplies purchased with this award become the property of the recipient institution.
5. **Notification:** Letters of notification will be sent in June of the award year. Please do not call the office prior to this time to inquire about the results.
6. **Start Date:** The recipient(s) of the Maureen Hanley Research Grant will be announced publicly at the closest AAO-HNSF Annual Meeting & OTO Expo immediately following the award. The award may be activated as early as July 1 of the year of award, **but no later than January 1 of the following year.**

### **F. FORMAT**

Applications are in a similar format to the National Institutes of Health. All applications must be completed and submitted online through Proposal Central at <https://proposalcentral.altum.com>. Visit <http://www.entnet.org/CORE> for more information on the application process.

### **G. SIGNATURES**

Foundation grants are legally awarded to the institution with which the Principal Investigator is affiliated, not to the investigator or his/her division or department. For this reason, it is very important that applicants comply with their home institutions' policies with regard to pre-submission processing of grant applications. This can take time, so it is wise to plan ahead, allowing adequate time for processing and approvals. For example, the original copy of an application to the Foundation must be signed by the person legally authorized to represent the institution in any contractual relationship that might result. This is typically someone in the administration whom the applicant does not know personally. Applicants are advised to consult their institutions' offices of research administration or sponsored projects for information on processing requirements for an application prior to its submission.

### **H. APPROVALS**

If the proposed research involves human subjects or vertebrate animals at any time, the project must be reviewed and approved by the appropriate institutional review board (IRB). This approval shall be obtained prior to submission and submitted with the application. If such approval is unavoidably delayed, enter "pending" instead of the data, upload the information provided to your IRB committee to your application and send a follow-up certification of approval signed by an official of the application institution within 30 days after the grant submission deadline. Grant applications which are not supported by evidence of the appropriate IRB documentation or approvals will not be reviewed or considered further in that grant cycle. Any changes in the proposed work required by an IRB to secure approval must be submitted to the Foundation with the follow-up certification, prior to review or after the work is in progress.

### **I. LETTER OF INTENT**

All applicants must submit a Letter of Intent online no later than midnight Eastern Standard Time December 17<sup>th</sup>, 2018. The letter of intent includes the title of the project, the principal investigator, and an abstract of the work. This will facilitate planning review requirements. See the proposalCENTRAL website (<https://proposalcentral.altum.com>) to begin the letter of intent process.

### **J. RECEIPT DATE**

Allow yourself enough time to have the appropriate individuals review your application. Once your application is complete, print your cover page and have all of the necessary individuals sign. Keep in mind that it may take a few days to obtain all of the necessary signatures. The CORE grants program is paperless, so no hard copies of the signature page are to be mailed. Once all signatures have been obtained, you should scan the document

and upload the .pdf to the system and retain the original for your files if needed. Once the signature page has been uploaded, run the checks within the system and click 'SUBMIT.' You will receive a confirmation email indicating that your proposal has officially been submitted.

**ALL materials must be submitted online by midnight, Eastern Standard Time, January 15<sup>th</sup>, 2019.**

### **K. FOLLOW-UP**

In carrying out its stewardship of research programs, AAO-HNSF may request information essential to an assessment of the effectiveness of this program. Accordingly, the recipient is hereby notified that s/he may be contacted after the completion of the award for periodic updates on various aspects of employment history, publications, support from research grants or contracts, honors and awards, professional activities, and other information helpful in evaluating the impact of the program.

### **L. REPORTING REQUIREMENTS**

Recipients of the Maureen Hannley Research Grant are required to complete an interim report at 6-months. Within 30-days of the completion of the project, the grantee will submit a final report. A final financial report must be submitted within 90 days of the close of the project. The results of the supported investigation must be submitted for presentation at the closest AAO-HNSF Annual Meeting & OTO Expo immediately following the award and are required to submit for publication in *Otolaryngology Head and Neck Surgery*. Submission does not guarantee acceptance. The AAO-HNSF simply has the right of first refusal given it is funding the research. Any presentation or publication of results supported by this award shall acknowledge the contribution of the AAO-HNSF Maureen Hannley Research Grant.

## **APPENDIX 1**

### **Examples of Appropriate Projects**

"Research gaps" are areas within the scope of clinical practice where key knowledge and data are missing that would prove useful in guiding and informing appropriate and effective patient care. Applicants for the Maureen Hannley Research Grant are strongly encouraged to consider project areas that could address a research gap within Otolaryngology. A list of possible research needs as listed in AAO-HNSF clinical practice guidelines published in *Otolaryngology-Head and Neck Surgery* that would potentially address a research gap are listed below for the applicant's consideration. These are merely suggestions of appropriate types of projects. The applicant is **not** required to choose one of these areas and instead may choose to study **any** area within Otolaryngology and its related specialties. To view these research gaps listed by subspecialty, go to <http://www.entnet.org/content/clinical-practice-guidelines> and click on "Research Gaps".

**Pediatric Otolaryngology** (Source: Clinical Practice Guideline for Otitis Media with Effusion (OME).

- 1) Assess the performance characteristics of pneumatic otoscopy as a diagnostic test for OME when performed by primary care physicians and advanced practice nurses in the routine office setting.
- 2) Evaluate the causal role of atopy in OME.
- 3) Define the role of adenoidectomy in children aged 3 years or younger as a specific OME therapy.

**General Otolaryngology** (Source: Clinical Practice Guideline for Cerumen Impaction. [Visit research needs page](#) for complete listing.)

- 1) A longitudinal study documenting the likely outcome of cerumen managed by observation alone that would guide clinicians as to the necessity of any intervention in the nonemergent setting.
- 2) Define the efficacy of prophylactic topical antimicrobials when EAC trauma occurs during cerumen removal.

3) Determine if different types or consistencies of cerumen should be managed differently.

**Rhinology** (Source: Clinical Practice Guideline for Adult Sinusitis. [Visit research needs page](#) for complete listing.)

1) Standardization of maximal medical therapy for chronic rhinosinusitis

2) Conduct clinical trials to determine the efficacy of an “observation option” for nonsevere sinusitis, by randomizing patients to immediate vs. delayed antibiotics and assessing clinical outcomes.

3) Development of a chronic rhinosinusitis treatment data registry

**Neuro-Otology** (Source Clinical Practice Guideline for Benign Paroxysmal Positional Vertigo. [Visit research needs page](#) for complete listing.)

1) Conduct prospective epidemiological studies of the incidence, prevalence, and burden of untreated BPPV among older adults.

2) Conduct diagnostic and cost-effectiveness studies to identify which subsets of patients, according to specific history or physical examination findings, should be submitted for additional vestibular testing and/or radiographic imaging in the setting of presumed BPPV.

3) Conduct epidemiological studies on the rates of fall with BPPV as an underlying cause/diagnosis. **APPENDIX 2**

### UTILIZATION OF THE CREATING HEALTHCARE EXCELLENCE THROUGH EDUCATION AND RESEARCH (CHEER) NETWORK

#### [Creating Healthcare Excellence through Education and Research](#)

#### **The CHEER Network – a National Resource for Practice-Based Research in Otolaryngology**

The CHEER network’s mission is to become the national resource for practice-based clinical research in disorders of the ear, nose and throat; translate the latest evidence into practice efficiently and expeditiously; and ultimately improve patient care [1]. “CHEER provides research infrastructure that will enhance the research experience for the researcher, collaborator, and patient [2].” CHEER defines practice-based research as a peer to peer collaboration affiliated in mission to investigate questions that seek to increase and improve medical evidence for effectiveness and quality of care in the ambulatory-based practice setting. Similar to the Agency for Healthcare Research and Quality, we believe that this definition includes a sense of ongoing commitment to network activities and an organizational structure that transcends a single research project. Practice-based research networks often link practicing clinicians with investigators experienced in clinical and health services research, while enhancing the research skills of the network members.

CHEER is comprised of 24 private and academic sites around the country committed to practice-based research and improving outcomes. Across our sites, we have over **200 otolaryngologist-head and neck surgeons, 100 audiologists, 50 speech language pathologists**, and many other office and professional staff dedicated to our mission. Our site study coordinators and private and academic investigators are the lifeblood to CHEER.

The CHEER infrastructure is funded by the **National Institute of Deafness and other Communication Disorders (NIDCD)** through mid-2017. We have a partnership with the **American Academy of Otolaryngology-Head and Neck Surgery Foundation**, the professional society for otolaryngology comprised of **12,000 members**,

furthering CHEER's reach and impact. ***We are actively pursuing other partners interested in supporting a sustainable model for practice-based research in otolaryngology and improved patient care.***

### **WHY PRACTICE-BASED RESEARCH?**

#### **The Importance of Practice-Based Research Networks and Community-Based Research**

*"If we want more evidence-based practice, we need more practice-based research."* [3]

There is general agreement that problems exist in the application of new science into clinical study AND that new and important clinical study information is poorly translated into practice. This is the roadblock that impedes development and dissemination of best practices in the US health care system [4]. While a number of solutions have been offered, most stakeholders agree that any solution must have certain common characteristics: 1) Increased public understanding, confidence, and participation in patient-oriented research. This includes community-based practitioners, their patients, representatives of third-party payer organizations and leaders of healthcare organizations; 2) An adequately trained and diverse workforce maintained in an environment that nurtures their ongoing career development; 3) An enhanced biomedical informatics base for clinical investigation, including data standards and central databases; and 4) Adequate and ongoing funding to support the infrastructure and administration of a clinical research enterprise that has a focus on effectiveness of treatments [1,4]. The practice-based research network (PBRN) has been widely advocated as one way of building capacity to efficiently bring clinical research to health care. It is in this environment where the relevant clinical questions are more likely to be generated and the relevant patient populations are served [1]. This community-based approach contrasts the efficacy endpoints of the randomized clinical trial (RCT) often funded by the pharmaceutical industry seeking a new profitable therapeutic intervention. The misalignment between effectiveness and efficacy can result in a lack of relevance between the published literature and what practitioners find useful to implement in the care of patients. This paradox must be bridged to address the public health needs in the United States. The PBRN can help address these issues through collaborations across the health care environment.

One of the most significant barriers to the successful implementation and development of the PBRN is the active and ongoing engagement of community practitioners. Even though many clinicians demonstrate an initial enthusiasm to be involved in research efforts, they often lack the administrative skills and knowledge to be effective participators. This may result in study delays, regulatory mishaps, cost overruns, and frustrations regarding the ease of integration of clinical research into clinical practice and is an important lesson from many PBRNs.

- 1.) AAFP. Practice-Based Research Networks in the 21st Century: The Pearls of Research. 2001.
- 2.) Tunis, S.R., A clinical research strategy to support shared decision making. Health Aff (Millwood), 2005. 24(1): p. 180-4.
- 3.) Green, L.A., et al., Opportunities, challenges, and lessons of international research in practice-based research networks: the case of an international study of acute otitis media. Ann Fam Med, 2004. 2(5): p. 429-33.
- 4.) Crowley, W.F., Jr., et al., Clinical research in the United States at a crossroads: proposal for a novel public-private partnership to establish a national clinical research enterprise. JAMA, 2004. 291(9): p. 1120-6.

### **RECENT PUBLICATIONS & PRESENTATIONS**

Witsell D, Rauch S, Tucci D, Telian S, Roland P, Nguyen-Huynh A, Schulz K. The Otology Data Collection Project: Report from the CHEER Network. *Otolaryngology – Head and Neck Surgery*. 145(4): 572-80, 2011. [PMID: 21771950]

Witsell D, Schulz K, Tucci D. Implementation and Testing of Research Infrastructure for Practice-Based Research in Hearing and Communication Disorders. *Otolaryngology – Head and Neck Surgery*. 145(4): 565-71, 2011. [PMID: 21593460]

Schulz K., Witsell D, Tucci, D. Proof of Concept: Effective and Expedient Deployment of a Community-based Research Network for Collecting Grant Pilot Data in Tinnitus and Dizziness. Association for Research in Otolaryngology, Baltimore, Maryland, February 19, 2011.

Tucci D, Schulz K, Witsell D. Building a national research network for clinical investigations in otology and neurotology. *Otology Neurotology*. 31(2): 190-5, 2010. [PMID: 20101159]

**IF YOU THINK YOUR STUDY IS APPROPRIATE FOR THE PRACTICE-BASED SETTING AND WOULD BENEFIT FROM ADDITIONAL SITES, CHEER MAY BE ABLE TO PROVIDE SUPPORT (PENDING SIGN-OFF ON APPROPRIATENESS BY THE CHEER LEADERSHIP GROUP). CONTACT KRIS SCHULZ AT [KRISTINE.SCHULZ@DUKE.EDU](mailto:KRISTINE.SCHULZ@DUKE.EDU) FOR MORE INFORMATION.**