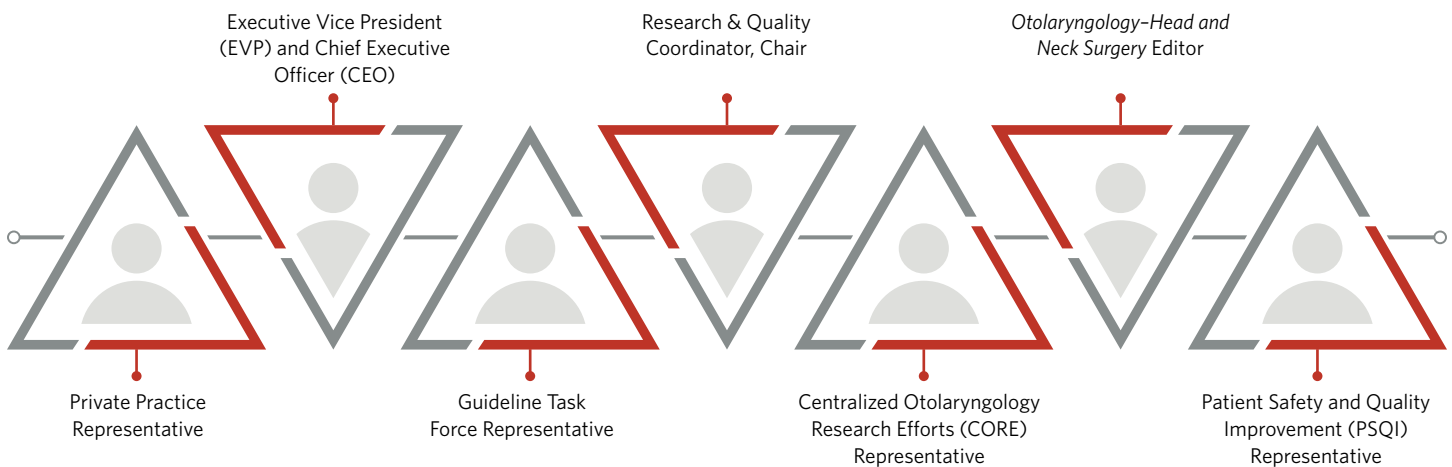


## POLICIES AND PROCEDURES

A Reg-ent Research Advisory Group (RRAG) has been formed to evaluate research proposals requesting data sets from the Reg-ent clinical data registry. The charge of the RRAG will be to promote the highest quality internal, non-commercial Reg-ent-associated research to ensure the advancement of the field of otolaryngology-head and neck surgery. The RRAG will be responsible for the review and prioritization of study proposals to include evaluation of scientific merit, feasibility, ethical considerations, and clinical relevance.

### REG-ENT RESEARCH ADVISORY GROUP (5-Year Terms)



### ELIGIBILITY/CONDITIONS FOR REG-ENT RESEARCH

- ✓ AAO-HNS/F member
- ✓ Contribute full data (structured, unstructured, and ancillary data) to Reg-ent; (Committee sponsored research will be exempt from this requirement)
- ✓ Proposals submitted by external entities will be reviewed by the RRAG and then go through the Executive Committee (EC) for final approval. Commercial proposals go through OM1 following contractual guidelines.

### STUDY PRIORITIZATION

Identified AAO-HNS/F knowledge gaps as put forth by Reg-ent Executive Committee (REC), Executive Committee (EC)/Board of Directors (BOD), CORE and Guidelines Task Force (GTF).

**Feasibility:** based on proposal score which takes into consideration:

- Significance/Clinical Impact
- To meet the needs of the specialty as determined by the BOD
- AAO-HNS/F Knowledge gap
- Achievability of protocol
- Methodology
- Timeline
- Principal Investigator (PI)/Collaborators research experience
- History of AAO-HNSF committee involvement and support

## SUBMISSION PROCESS

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1. Requests for Reg-ent data will be made to the Reg-ent Research Advisory Group through [Reg-ent Research Data Request Form](#) (see Reg-ent Data Access Toolkit).
2. Signed Acknowledgment that Reg-ent associated research will be submitted for publication to *Otolaryngology-Head and Neck Surgery* or *OTO Open* for right of first refusal and to the Annual Meeting Program Committee (AMPC) for presentation at the AAO-HNSF Annual Meeting.
  - a. Final publication of Reg-ent related research is subject to the standard peer-review process and final disposition is rendered by the Editor in Chief of *Otolaryngology-Head and Neck Surgery*.
  - b. At the direction of the journal editor, waivers will be considered by the AAO-HNS Executive Committee following referral from the REC for manuscripts warranting a higher-impact journal with widespread readership (e.g., JAMA, New England Journal of Medicine, Cancer, etc.) or a subspecialty journal outside of otolaryngology and for presentations outside the AAO-HNSF Annual Meeting.
3. If a submission is rejected by *Otolaryngology-Head and Neck Surgery* or *OTO Open*, it can be submitted to another peer-reviewed journal.
4. PI is responsible for Institutional Review Board (IRB) approval which must be included **at the time of** proposal submission.
5. Applications will be accepted on a rolling basis.
6. Members of the RRAG will complete the proposal review webform and submit to the RRAG liaison for collation.
7. When necessary, the RRAG will correspond via email and/or conference call if there are significant concerns or discrepancies with a submission.
8. The RRAG Chair will provide recommendations on Reg-ent research proposals to the REC. The AAO-HNS Executive Committee will render the final decision to the PI on REC-approved proposals.

## POST APPROVAL

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- Research proposal (title and study type) will be published on the Reg-ent website to avoid duplication of research efforts.
- The PI is responsible for submitting a biannual research update including a projected timeline to completion to the RRAG. (Additionally, major changes should be communicated to the RRAG in a timely fashion).
- Presentation of Reg-ent related research: If Reg-ent generated research is planned for presentation at an otolaryngology specific meeting, the AAO-HNS/F Annual Meeting must be given right of first refusal unless otherwise waived by the AAO-HNS Executive Committee.

**Revenue Generating Projects:** OM1 is responsible for reviewing study design and IRB. This is for projects which fall within our mission only. A list of revenue generating projects will be provided to the OM1 AAO-HNSF Steering Committee on a semi-annual basis.

**IRB, non-Revenue Generating Organizations:** Conduct projects through their institution's IRB. IRB approval is needed in advance of submission (as stated above in the Submission Process section).

**Reg-ent Website Homepage:** Will list approved projects (will not include the investigator, just project name). The website will include a list of Reg-ent sections and elements that are available by category type. This is also available through the Data Access Toolkit.

**Timeline:** A 3-month notification for developing applications will be provided and then approval process could take up to 6-8 months. We can then proceed to a rolling process.

**Committee Proposals:** AAO-HNS committees are provided the opportunity for submitting one project annually. If more are requested, these must go through the Executive Committee of the Board.