



REG-ENT DATA ACCESS TOOLKIT



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Overview

The Reg-ent clinical data registry is the first national data repository of otolaryngology-specific clinical data. Reg-ent equips otolaryngologist-head and neck surgeons with a large data repository to improve quality patient care and outcomes. After evolving from an initial phase of meeting members needs as a vehicle for public reporting to the Centers for Medicare and Medicaid (CMS) Merit-based Incentive Payment System (MIPS), Reg-ent is now fully expanded to the phase two goal of providing our members the opportunity to utilize big data from the Reg-ent de-identified patient data set for research and quality improvement projects.

Our commitment is to have high quality research projects, reviewed, prioritized and approved by the Reg-ent Advisory Panel for Innovation & Development (RAPID), utilizing Reg-ent data sets addressing a wide variety of research projects. Only projects which fall within the AAO-HNS mission will be accepted.

AAO-HNS has partnered with Matrix, a leading data analytics organization to aid in the expansion to phase two.

Eligibility/Conditions for Reg-ent Research

- AAO-HNS/F member
- Contribute full data (structured, unstructured, and ancillary data) to Reg-ent
 - AAO-HNS/F committees are provided the opportunity to submit one project annually that is exempt from Reg-ent membership. If more are requested, these must go through the Executive Committee of the Board.

Study Prioritization

- Identified AAO-HNS/F knowledge gaps as put forth by RAPID.
- 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

Data Access

Reg-ent is currently accepting proposals for non-commercially funded projects. A data request form is completed and submitted at <https://www.entnet.org/reg-ent-research-request-form/> (you have to be logged in as a member to view the form). The initial review of data request forms is completed by Reg-ent staff before completed forms are submitted to RAPID.

Submission/Approval Process

1. Requests for Reg-ent data will be made to RAPID utilizing the [Reg-ent Research Data Request Form](#). You have to login to your AAO-HNSF account first to be able to view the form.
2. Signed acknowledgement 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 AMPC for presentation at the AAO-HNS Annual Meeting is required.
 - a. Final publication of Reg-ent related research is subject to the standard peer-review process and final disposition is rendered by the Editor- chief of *Otolaryngology-Head and Neck Surgery*.
 - b. Waivers will be considered by the AAO-HNS Executive Committee following referral from the Reg-ent Executive Committee 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-HNS 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. Principal Investigator (PI) must provide agreement to utilize central Institutional Review Board (IRB); if centralized IRB is not utilized, PI is responsible for institutional IRB approval which must be included at the time of proposal submission.
5. Applications will be accepted on a rolling basis.
6. Once Reg-ent staff have assessed the proposal for feasibility, they will send a deidentified copy to RAPID for review.
7. When necessary, Reg-ent staff will email any significant concerns or discrepancies with a submission.

Post Approval Process

1. Reg-ent staff will notify the researcher over email about their approval.
2. Reg-ent staff will have a discovery call with the PI to go over the specifics of the research questions/criteria, inquire if any analytical support is needed, confirm which clinical tables will be delivered, and ask which file format (CSV file dump or DB file) the research team prefers.
3. After the discovery call, Reg-ent staff will send an Excel spreadsheet with all the codes listed in the proposal/discussed in the discovery call for approval. If analytical support is needed, staff will send a consultation contract (pricing, hours). Staff will also send a data use agreement to the researcher that needs to be executed prior to receiving the data.
4. Research proposals (title; study type; involved committees/institutions/investigators; progress) will be published on the Reg-ent website to avoid duplication of research efforts.
5. The PI is responsible for submitting quarterly research updates, including a projected timeline to completion to staff.
6. Presentation of Reg-ent related research: If Reg-ent generated research is planned for presentation at an otolaryngology-specific meeting, the AAO-HNSF Annual Meeting must be given right of first refusal unless otherwise waived by the AAO-HNS Executive Committee.