



EMORY
UNIVERSITY

OTO-SURG 1

**A Prospective Evaluation of Worldwide
Tonsillectomy Indications, Techniques, and
Outcomes**

**Study Protocol v1.5
October 22, 2025**

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BACKGROUND/RESEARCH GAP:

Tonsillectomy is the most common pediatric surgery worldwide; yet, little is known about how tonsillectomy outcomes vary globally, especially in low- and middle-income countries (LMICs). While generally considered a safe procedure, with mortality rates in high-income countries (HICs) being relatively low (~0.0005%), mortality rates in LMICs are poorly characterized and may be as high as 3%.

To date, no prospective global studies have been attempted to assess and understand worldwide pediatric tonsillectomy trends and outcomes.

HYPOTHESIS AND SPECIFIC AIMS:

We hypothesize that the morbidity and mortality associated with routine tonsillectomy, as well as surgical indications and techniques, vary significantly across different geographic regions and healthcare settings.

Primary Aims:

- **Characterize** pediatric tonsillectomy surgical indications and techniques across the World Health Organization (WHO) regions.
- **Quantify** global pediatric 30-day post-tonsillectomy complications and mortality.

Secondary Aims:

- **Recruit and train** a collaborative research network of otolaryngology surgeons and trainees from around the world who will be poised to carry out future research projects.
- **Build the digital infrastructure** necessary to support this network in a sustainable manner.

CONSENT PROCESS:

This research involves no intervention or alteration to patient care. Therefore, there is minimal risk to participants. For these reasons, the Emory IRB was granted a waiver of informed consent. Medical records will be reviewed, and only de-identified clinical data will be recorded in REDCap, ensuring that there is no potential for physical, psychological, or social harm to participants. **We will work closely with partner sites to navigate local IRB processes, which may have different requirements for informed consent and data collection.**

DESIGN:

This is a **global prospective, multi-site, de-identified, observational study** aimed at establishing a global data registry of pediatric tonsillectomy indications, techniques, and outcomes.

All healthcare centers worldwide that perform pediatric tonsillectomies are invited to participate in this study. Investigators will be trained to collect and input de-identified data into the REDCap database over a pre-defined data collection period.

A **hub-and-spoke model** will be utilized, with the **Global OHNS Initiative** and **Emory University** serving as the central hub, linking to individual partner institutions from participating sites.

Each participating site will **develop a research team with two to four investigators.** One representative will be designated as the team lead and will serve as the liaison between the partner site and the central hub.

All sites are responsible for developing appropriate data collection mechanisms for their respective institutions to include all eligible patients. We will provide **site-specific support** to help our partners obtain IRB approval and access the REDCap database.

To ensure that data is globally diverse and representative, we aim to recruit **at least 30 individual sites from each of the six WHO regions.** There is no minimum number of recorded patients per center, and no limit to the number of partner sites within a WHO region or country.

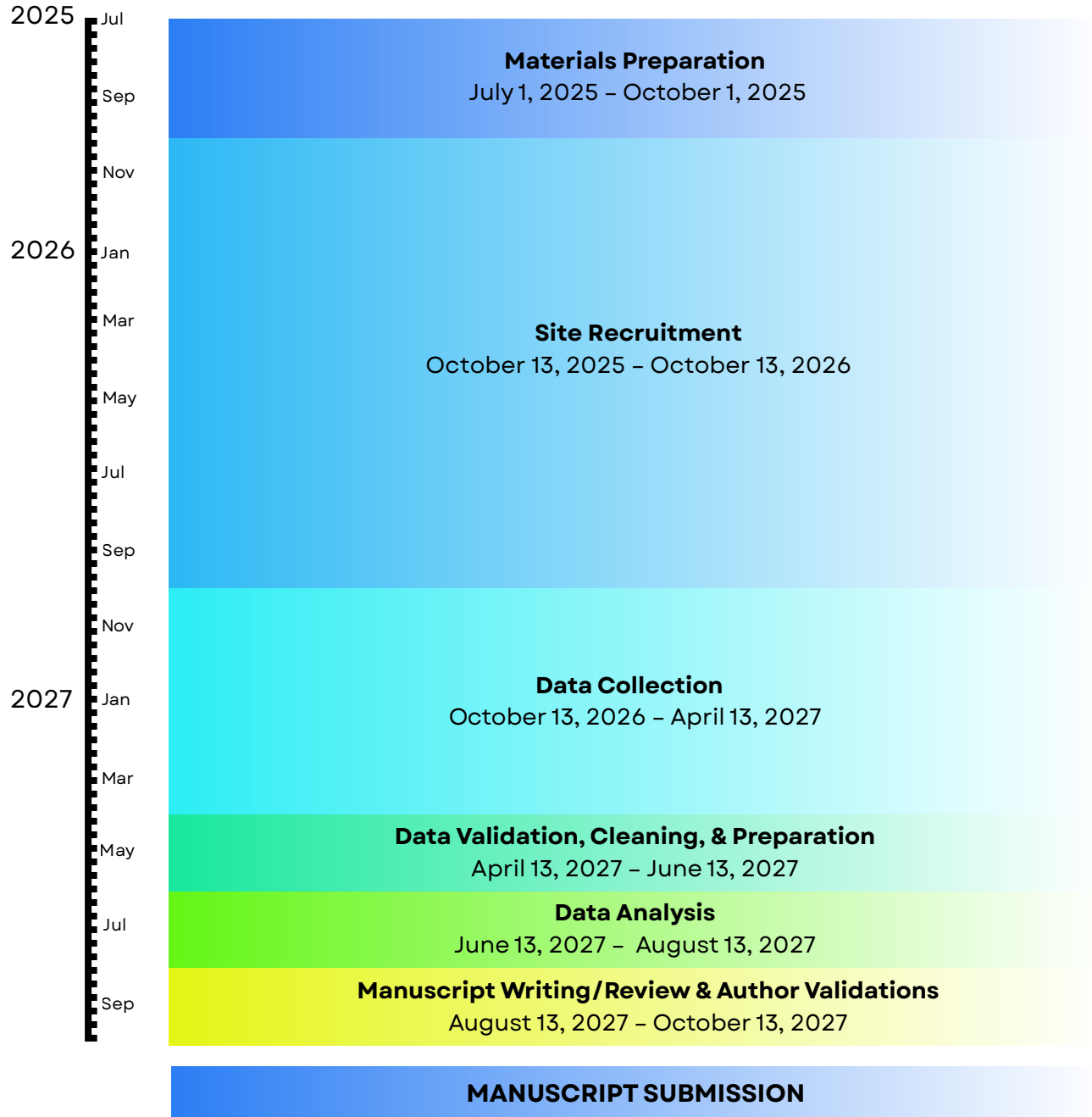
All contributors will be eligible for authorship.

This prospective, multi-site, international assessment of worldwide tonsillectomy outcomes aims to standardize post-operative information for the world's most common pediatric surgery while collecting representative data from LMICs.

This collaborative research network will lay the foundation for vibrant and active global engagement on future large-scale initiatives and data-driven interventions.

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PROJECT TIMELINE:



CONTACT INFORMATION:

Interested in representing your site in OtoSurg-One?
Have any further questions/concerns?

Please don't hesitate to reach out to our leadership team by email at otosurg.recruitment@gmail.com, or join our WhatsApp group using this QR code!

