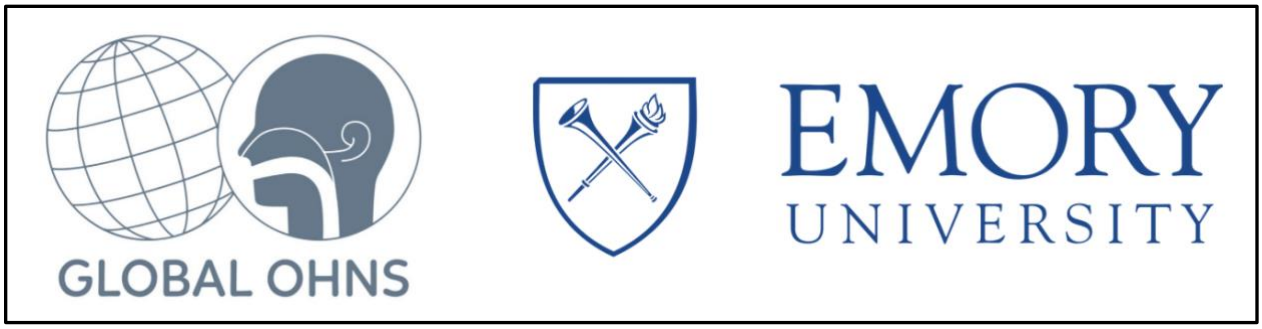

OtoSurg 1

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

IRB Toolkit v2.4
February 7, 2026

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OtoSurg1 IRB Toolkit

This document is intended to assist individuals responding to IRB questions across various institutions. Please review the table of contents as you are completing the IRB application at your home institution.

You may copy and paste text from this document directly into your IRB application to streamline the application process. However, please be sure to provide institution-specific information where appropriate. We have identified several areas in this document where institution-specific information is required by highlighting the text in yellow: [EXAMPLE]

We recommend that all participating institutions apply for **expedited IRB review**, if eligible, designating **your institution** as the IRB of record for this application.

We have aimed to address as many sections and questions from the IRB application process as possible, including an additional FAQ section at the end of the document. However, we recognize that further inquiries may arise that are not addressed in this document.

If you have any questions or concerns regarding the IRB application process that are not answered by this toolkit, please get in touch with the Research Support Team at otosurgohns@gmail.com.

1. Project Summary

Project Title:

Oto-Surg 1: Building a De-identified Registry to Assess Global Tonsillectomy Indications, Techniques, and Outcomes

Project Design:

Prospective, multi-site, international, de-identified, observational data registry

Primary Objective(s):

Build a de-identified data registry of prospectively collected data regarding tonsillectomy outcomes with the primary aims of:

1. Characterizing pediatric tonsillectomy surgical indications and techniques across World Health Organization (WHO) regions
2. Quantifying global pediatric 30-day post-tonsillectomy complications and mortality

Secondary Objective(s):

Build a de-identified data registry of prospectively collected data regarding tonsillectomy outcomes with the secondary aims of:

1. Recruiting and training a collaborative research network of otolaryngology surgeons and trainees from around the world who will be poised to carry out future research projects
2. Building the digital infrastructure necessary to support this network sustainably

Research Intervention(s)/Interactions:

Participating investigators at participating sites will be trained to collect and report de-identified data on pediatric patients undergoing tonsillectomy over a 60-day period at their respective institutions. They will record de-identified demographic data, surgical indication(s), surgical technique(s), post-operative complications, and mortality directly into REDCap.

Study Population:

The study population will include all consecutive patients younger than 18 years of age undergoing tonsillectomy during the selected registry period at the participating site.

Study Duration for Individual Participants:

There is no specific study duration for participants. Their de-identified information will be input into a REDCap database.

Study Specific Abbreviations/Definitions:

Tonsillectomy will be defined as the removal or ablation of any amount of tonsil tissue using any surgical technique. High-income countries (HICs) are defined as those with a gross national income per capita of greater than $14,005 USD. Low- and middle-income countries (LMICs) are defined as those with a gross national income per capita less than $14,005 USD.

Funding Source (if any):

None.

2. Background

Although generally considered a safe surgery, tonsillectomy carries significant risks for children. Approximately 3% of children require hospital readmission within 30 days due to life-threatening complications[1]. While mortality rates in high-income countries (HICs) are low (~0.0005%), mortality rates in low- and middle-income countries (LMICs) are not well characterized, with some reports suggesting rates that are orders of magnitude higher (~3%)[2–4]. New techniques such as intracapsular tonsillectomy and coblation tonsillectomy may reduce the incidence of complications[5–9]. However, it is unclear how these techniques are utilized across different settings and whether they are associated with specific postoperative outcomes.

The indications, techniques, and postoperative outcomes for pediatric tonsillectomy are well documented in the United States (US), as evidenced by the updated clinical practice guideline from the American Academy of Otolaryngology – Head and Neck Surgery, published in 2019[10]. A 2015 systematic review and meta-analysis of adenotonsillectomy complications identified respiratory compromise and secondary hemorrhage as the most common early complications globally[2]. However, country-specific clinical practice guidelines and investigations of postoperative complications remain limited in many settings. Several reports in the literature provide insight into current practices in LMICs: for example, Muninnobpamasa et al. described the prevalence of post-tonsillectomy complications at a single institution in Thailand; Kligerman et al. found that tonsillectomy (with or without adenoidectomy) was the most frequently performed otolaryngologic surgery at a single institution in Haiti; and Onotai et al. reported that preoperative blood grouping and cross-matching before adenoid and tonsil surgeries were often

not cost-effective or relevant in most circumstances at a single institution in Nigeria[3,11,12]. Additional reports from HICs highlight knowledge gaps: For example, Murto et al. identified that rates of adverse post-adenotonsillectomy outcomes and associated factors were poorly described in Canada, indicating a need for standardized perioperative treatment algorithms[4].

Building on this background, OtoSurg 1 will be an international, multi-site, prospective cohort study that will describe global variations in indications, techniques, and outcomes for pediatric tonsillectomy. Additionally, this study will provide a framework for future multinational, prospective collaborations to be replicated across the global otolaryngology research community. Ultimately, this research network is intended to improve access to high-quality otolaryngology care globally.

3. Objectives

Primary Objective(s):

Build a de-identified data registry of prospectively collected data regarding tonsillectomy outcomes with the primary aims of:

1. Characterizing pediatric tonsillectomy surgical indications and techniques across World Health Organization (WHO) regions
2. Quantifying global pediatric 30-day post-tonsillectomy complications and mortality

Secondary Objective(s):

Build a de-identified data registry of prospectively collected data regarding tonsillectomy outcomes with the secondary aims of:

1. Recruiting and training a collaborative research network of otolaryngology surgeons and trainees from around the world who will be poised to carry out future research projects
2. Building the digital infrastructure necessary to support this network sustainably

4. Project Design, Setting, and Site Eligibility

OtoSurg 1 will be an international, multi-site, prospective observational cohort study. This study will follow a methodology similar to that previously developed and implemented by GlobalSurg[13,14]. The OtoSurg Leadership Team will consist of three groups: Recruitment and Publicity, Research Support, and Data Management and Analytics. The Recruitment and Publicity Team will oversee all WHO regional leads, individual country leads, and specific hospital teams. The Research Support Team will manage the onboarding process for new OtoSurg members, develop educational materials, and assist with IRB and REDCap use. The Data Management and Analytics Team will collect, validate, and analyze all study data. By working closely together, these three core teams will serve as the organizational framework of OtoSurg 1.

The broader OtoSurg network will be organized utilizing a hub-and-spoke model, with the Global OHNS Initiative and Emory University serving as the central hub, linking to regional representatives across the six WHO regions and individual researchers at country-specific partner sites. Emory University will serve as the research network's database repository, linking to individual researchers from participating sites. Any healthcare facilities worldwide where pediatric tonsillectomies are performed will be eligible to participate (except sites in China due to the Personal Information Protection Law (PIPL) of the People's Republic of China). The study will aim for balanced representation from each of the six WHO regions. Each research site must have at least two investigators, including at least one Data Recorder and one Data Validator. Larger teams will be permitted, with a maximum of four members. Each team will appoint a

team leader who will serve as the primary point of contact with the central hub. Participating sites must obtain independent IRB approval or exemption and have access to the shared REDCap database. Aside from these requirements, there are no strict inclusion or exclusion criteria for sites. There is no minimum number of patients required to be recorded per facility or healthcare setting. Every member of each research team will be listed as an author on the final manuscript, except those who do not meet the data validation criteria outlined below.

Each participating site will prospectively collect and record data over a consecutive 60-day period of its choosing within the overall 6-month data collection window. The database building period is predicted to run from October 13, 2026, to April 13, 2027. Participating teams will implement site-specific strategies to ensure the identification and inclusion of all eligible patients. These strategies may include daily review of operating room logbooks, multidisciplinary team meetings, and review of surgical admission or handover lists. Patient-level data will be obtained through a review of medical records, discussions with clinical team members, or, where appropriate, communication with patients and their families. All data will be deidentified and recorded directly into REDCap by the dedicated Data Recorder(s) from each participating site. The following patient data will be collected: age, sex, anesthesia preoperative risk class, tonsillectomy indication, tonsillectomy technique (intracapsular vs extracapsular; Bovie vs coblator vs microdebrider vs cold steel vs other), 30-day postoperative major complications, and 30-day postoperative mortality. In addition, data on participating sites will be collected, including the WHO region, country, the WHO health care facility level, and the country's World Bank income group[15]. The data variables and specific survey questions were developed using iterative feedback from representatives of each of the six WHO regions.

The reason there is a range of dates available (October 13, 2026, to April 13, 2027) instead of a single 60-day period is to be as inclusive as possible for participating sites. Participating sites may have a conflict with a specific pre-set data collection period. By providing a broad range of dates, we can ensure flexibility for sites interested in participating.

Collecting data prospectively instead of retrospectively is crucial to ensuring data completeness, consistency, and accuracy across all participating sites. A prospective approach allows for the standardized collection of key variables, ensuring that all sites document the same data points in a structured manner. This is especially important, as this study will emphasize participation from international sites, where variations in record-keeping systems could introduce challenges in obtaining uniform data. Retrospective data collection would likely lead to higher rates of incomplete datasets, which could, in turn, lead to confounding of results.

Furthermore, prospective data collection enables more active and systematic tracking of post-operative complications, which may not always be well-documented in retrospective chart reviews. In many healthcare settings, especially those with limited resources, follow-up data on complications may be difficult to find or access unless there is a dedicated effort to capture this information in real time. By collecting data prospectively, we can ensure that these outcomes are systematically monitored and accurately recorded, improving the reliability of our findings and allowing for meaningful comparisons across sites.

5. Data Monitoring and Quality Assurance

Each participating site will designate one team member as the Data Validator. This person will independently record the total number of tonsillectomy cases that meet the inclusion criteria during the specified data collection period at their site. This total will be referred to as the total case ascertainment. Data Validators can gather this information either prospectively or retrospectively, depending on what is most practical for their site's workflow and record-keeping systems. Sites missing data for more than 20% of patients included during their 60-day collection period will be excluded from the final analysis and will be ineligible for authorship.

The Data Validator will be randomly assigned five cases from their team to review. The Data Management and Analytics team will randomly assign these cases and provide the Data Validator with the submitted data. If fewer than five cases are available, all eligible cases will be reviewed. To perform the review, the Data Validator will obtain the de-identified study data and the local linkage file from the Data Recorder, which will be in the form of a Microsoft Excel file or a hard copy paper file. Using this information, the Data Validator will conduct a retrospective chart review for these cases to evaluate the accuracy and completeness of the recorded data. The Data Validator will submit a separate, password-protected REDCap survey link provided by the OtoSurg team. This survey will ask the Data Validator to assess the accuracy and completeness of the recorded data and determine if patients had postoperative follow-up.

This is a collaborative project where Emory University does not fund in-country activities and does not subcontract in-country personnel. Instead, participants from participating healthcare

facilities will merely submit deidentified data from their specific institution. This process will be identical for sites inside and outside the United States.

6. Study Population and Inclusion/Exclusion Criteria

The study population will comprise all consecutive patients under 18 years old undergoing tonsillectomy during the specified study period at the participating site. Tonsillectomy will be defined as the removal or ablation of any amount of tonsil tissue using any surgical method. Both unilateral and bilateral tonsillectomy cases are eligible. Patients undergoing concurrent procedures, such as adenoidectomy or tympanostomy tube placement, will be included. Sites from any country worldwide are eligible to participate, excluding China.

7. Vulnerable Populations

While de-identified data on pediatric patients will be collected, this project will not require any specific interaction with pediatric patients, nor will it impact clinical care. It is simply a de-identified registry of tonsillectomy indications and techniques. We are not including adults unable to consent, pregnant women, or prisoners. Individuals with cognitive impairments or impaired decision-making capacity may be included in the de-identified data, but this is not the target population.

8. Recruitment Methods

An open invitation to participate in OtoSurg 1 will be broadly shared through personal contacts, professional email listservs, and existing national and international networks. Regional and country leads will be recruited who can provide a detailed site-specific understanding to support recruitment and training.

The OtoSurg team will provide research training and access to a shared REDCap database. They will also assist with participant recruitment and IRB processes. Training resources will include live webinars, PDF documents (including a dedicated IRB support guide), and pre-recorded videos developed for this study. Training materials will be offered in English, with translations into partner site languages as resources permit. Training materials will be hosted on a central website to facilitate access by participants globally.

9. Provisions to Monitor the Data to Ensure the Safety of Participants

This study is observational in nature, with no direct interventions impacting patient care. All data collected will be de-identified, minimizing risks to participants. Participating sites will have an open channel to report any concerns directly to the study coordinators at [INSERT NAME OF PARTICIPATING SITE HERE] regarding patient safety or unexpected events related to the study in real time. At the conclusion of the study, a comprehensive analysis will assess any regional or technique-specific disparities in outcomes and provide evidence-based recommendations to improve safety and outcomes in future tonsillectomy practice worldwide.

10. Data/Biospecimens Management

This study will collect only demographic and clinical data, excluding biospecimens. Data points include Patient age, sex, anesthesia preoperative risk class, tonsillectomy indication, tonsillectomy technique, 30-day postoperative major complications (such as post-operative hemorrhage, hospital re-admission, and the need for repeat surgery), and postoperative 30-day mortality. In addition, data on participating sites will be collected, including the WHO region, country, the WHO health care facility level, and the country's World Bank income group.[15]

All data will be securely stored in a REDCap database with encryption both at rest and in transit, and access will be restricted to authorized study team members using role-based permissions. Emory University REDCap will be the primary/master REDCap database with [INSERT NAME OF PARTICIPATING SITE HERE] as an authorized participating site. De-identified data will be transmitted through secure REDCap links, ensuring participant confidentiality. Per HIPAA guidelines, the data will be retained for a maximum of 7 years. No identifiable patient data will be collected, stored, or shared.

Concerning General Data Protection Regulations, Emory's RedCap will be used for data collection, with encryption. REDCap Data from the European Economic Area will be kept separate from data from the United States and other countries. Data will be accessed via connection to Emory University's VPN. The study team will notify the IRB and [INSERT SITE-SPECIFIC OFFICE OF RESEARCH COMPLIANCE/PROTECTION, IF AVAILABLE] of any data breaches. [INSERT SITE-SPECIFIC OFFICE OF RESEARCH

COMPLIANCE/PROTECTION, IF AVAILABLE] will work with the IRB and the study team on remedial measures on a case-by-case basis.

11. Informed Consent and Equitable Inclusion of Subjects

Each individual participating site needs to make its own determination regarding a waiver of consent in accordance with local IRB requirements.

1. **If Pursuing a Waiver of Consent:**

   If pursuing a **waiver of consent**, please use the following language:

   We do not expect informed consent to be necessary for this project because it is observational and involves collecting deidentified, routinely recorded clinical data without any intervention or changes to patient care. Therefore, there is minimal risk to participants. The study cannot be conducted without a waiver, as requiring individual consent from a large and diverse patient population across multiple institutions would cause significant logistical challenges and introduce selection biases, ultimately compromising the project's integrity and feasibility. We also believe that obtaining informed consent for a study of this nature, which is already very low risk, would likely result in unnecessary confusion and anxiety. Although the study uses clinical data, no identifiable private information is involved, ensuring participants' privacy is maintained. The waiver will not negatively impact the rights or welfare of the subjects, as their data will be securely handled, and no interventions or interactions with participants will occur.

2. **If Your Site Requires Informed Consent:**

Please refer to the OtoSurg website to access the OtoSurg 1 Participant Consent Form and OtoSurg 1 Participant Information Sheets for use at your institution.

3. **Equitable Inclusion of Subjects**

Non-English-Speaking Participants

This is not applicable because there is no direct interaction or contact with patients required for this project.

Participants who are not yet adults (infants, children, teenagers)

This is not applicable as informed consent is not anticipated for this project. See the above paragraph regarding informed consent.

Cognitively Impaired Adults

This is not applicable as informed consent is not anticipated for this project. See the above paragraph regarding informed consent.

Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)

12. Use of HIPAA Data and Rationale for HIPAA Waiver Request

No HIPAA information will be recorded; however, it will be accessed via chart review to obtain the appropriate data for the database. A waiver of informed consent is requested for this project.

Rationale for HIPAA Waiver Request

We believe a waiver of informed consent is valid for several reasons:

1. **Little/No Harm to Patients:**

   The research involves no more than minimal risk to subjects. Similar to most chart review studies, this project involves reviewing medical records, which by nature contain protected health information; however, no direct interventions, treatments, or interactions with participants will take place. The medical record will be reviewed, and de-identified data will be recorded directly into REDCap, ensuring that there is no potential for physical, psychological, or social harm to participants.

2. **Impracticality of Consent Process:**

   Requiring individual consent for this study would be impractical due to the large number of participating sites and the nature of prospective data collection across multiple institutions. Given the scale of the study, obtaining real-time consent from every eligible participant would place an excessive logistical burden on the research team, making it unfeasible to conduct the study efficiently. Patients present at different times and locations, including high-throughput settings such as pre-operative waiting areas, where

seeking consent may not be feasible without disrupting clinical workflows and delaying patient care.

3. **Introducing Selection Bias with Consent:**

   Requiring consent could introduce significant selection bias, as individuals who decline participation may systematically differ from those who agree, ultimately distorting study findings. This is particularly relevant for a study aiming to capture a representative patient population across diverse geographic and healthcare settings. If consent were required, participation rates could vary by region, hospital, or demographic factors, reducing the generalizability and validity of the research.

   Additionally, in many cases, potential participants are not identifiable in advance, as daily surgical records would need to be retrospectively reviewed to determine eligibility. The inability to prospectively pre-screen participants further complicates the consent process, making it impractical to obtain informed consent in a timely and efficient manner. Finally, requiring consent for a study that poses little to no risk could inadvertently cause unnecessary anxiety or confusion for patients and families, particularly in a pre-surgical setting where they may already be under stress. Given these considerations, a waiver of consent is essential to ensure the study's successful execution while maintaining scientific integrity and ethical research standards.

13. Risk to Participation

Minimal risk is anticipated with this project. It is possible that data could be improperly input into the REDCap database, resulting in a breach of confidentiality and anonymity. However, this is extraordinarily unlikely because the data collection device, shared with participating sites, will be produced and managed by Emory University and will contain only de-identified data elements. There could also be unintended data sharing if the registry data is improperly accessed or shared; however, REDCap has built-in security software to help protect against this.

14. Benefits to Future Subjects or Science

We highlight below two specific ways in which this project can contribute to knowledge that would strengthen pediatric otolaryngology outcomes:

1. **Development of National and International Outcomes Benchmarks.** Currently, practices vary widely, leading to inconsistent patient outcomes. By producing the first prospective global dataset on tonsillectomy outcomes, this registry can establish international benchmarks for complication rates, readmissions, and mortality. These benchmarks would serve as a reference for healthcare providers and policymakers, highlighting areas that need improvement. Countries and institutions could then measure their performance against these benchmarks, driving quality improvement initiatives and resource allocation to reduce disparities in care.

2. **Development of Risk Stratification Tools.** The large-scale data collected from this project can be used to develop tools that predict which patients are at higher risk for complications based on demographic, clinical, and procedural factors. Such tools would allow clinicians to individualize care, providing additional monitoring or interventions for high-risk patients. This personalized approach would improve safety and outcomes, especially in high-mortality regions, and enable resource optimization in low-resource settings.

15. Compensation

No compensation will be provided.

16. Confidentiality

No direct identifiers (e.g., name, date of birth, or medical record number) will be collected or stored. Data will be fully deidentified at the point of entry into the database, with only aggregated or anonymized information recorded.

Data collected from participating sites may initially use codes (e.g., patient study IDs) to link data during the collection process. However, the key linking these codes to identifiable information will remain exclusively with the participating sites and will not be shared with the central database. Each participating site will be responsible for securely storing this information.

The database will be hosted on REDCap, a secure, web-based platform designed for managing research data. REDCap is widely used for sensitive data management and complies with international privacy and security standards. Each participating site will receive unique login credentials with role-based permissions to ensure that only necessary personnel can access specific data.

17. Incidental Findings

Given the nature of this registry, which focuses on global pediatric tonsillectomy trends and outcomes, the likelihood of medically actionable findings at the individual level is minimal. No direct identifiers or study IDs linking participants to their data will be stored in the central database, which makes it impossible to share specific findings with individual participants. Furthermore, this registry is not designed to generate clinical diagnostic results or findings that could influence individual patient care.

18. Withdrawal of Participants

If a participating site is found to have violated protocols or ethical guidelines, data from participants at that site may be removed, and members of the associated research team may be excluded from the final authorship list.

19. Potential Recontact for Future Study Enrollment

Researchers from participating sites may be contacted to participate in future similar deidentified data registries. Individual patients, however, will not be contacted as no identifiable information is available at the individual level.

20. Access to Registry/Repository/Database

Access to data will be tightly controlled. Importantly, the registry will be completely anonymized, and no PHI will be recorded or included. Study members from each participating site will only be able to access and record their own site-specific data. Once submitted, this data will become part of the larger, comprehensive database housed in the Emory University REDCap system. Access to the complete database will be restricted to study members within the Emory University network and/or those explicitly granted permission by the IRB committee. The database will be password-protected. A data use agreement is not expected to be required because all data entered into the registry will be fully deidentified before sharing with investigators, and all data is incoming to Emory University.

21. Future Studies

No patient identifiers will be provided to other researchers, as no identifiable or linking information will be included with this database.

22. Protocol Checklist

If your institutional IRB requires a protocol checklist, please complete it using the information described in sections 1-20 above.

23. Appendix A: Supplemental Questions and IRB Language

1. **Personnel and Outside Collaborators:**

   If required to list **internal collaborators**, please list information about your site's complete internal team, including the site-specific PI, Data Recurder(s), Data Validator(s), and Team Lead.

   If required to list **external/outside collaborators**, please list the following: Zachary Elwell, MD, Taseer Din, MBChB, MMED, and Maxwell P. Kligerman, MD.

2. **Problem Statement:**

   If required to list a problem statement, you may use the language below as a template:

   Conducting meaningful global outcomes research in otolaryngology requires coordinated, large-scale collaboration across diverse healthcare settings. The GlobalSurg Collaborative (GlobalSurg) serves as a model for the design of this study. GlobalSurg, the product of the UK National Institute of Health Care Research's Global Health Research Unit on Global Surgery, is a robust international community that produces high-impact, prospective, multi-site research studies to advance surgical care.[16–18] In 2016, GlobalSurg published a landmark article assessing worldwide emergency abdominal surgery outcomes, establishing a precedent for the design of collaborative global international surgical outcomes research.[16] This study builds on the successful

GlobalSurg model and will help quantify potential disparities in global pediatric tonsillectomy outcomes.

3. **Description of the Global OHNS Initiative:**

If required to define/describe the Global OHNS Initiative, you may use the language below as a template:

The Global Otolaryngology-Head and Neck Surgery (OHNS) Initiative is a 501(c)(3) nonprofit organization that aims to perform global, collaborative public health research with the aim of better understanding and expanding access to otolaryngology care worldwide.[19] The Global OHNS Initiative has published expert consensus-based studies that identified priority global OHNS conditions and procedures in both adult and pediatric populations.[20,21] Examples of the procedures identified as global priorities were tonsillectomy, thyroidectomy, and tracheostomy. The significant and disparate global burden of otolaryngology conditions underscores the need to conduct robust international studies to identify opportunities for intervention and improve health outcomes.[22–24]

4. **Timeline**

If required to provide more detailed information on the study timeline, you may use the following language:

The study will begin with recruiting and training participating sites. Recruitment, training, and individual site IRB approval will occur over 12 months from October 13,

2025, to October 13, 2026 (Figure 3). The six-month data collection period will be from October 13, 2026, to April 13, 2027. Individual sites will be able to select any 60-day interval during this data collection window to record and submit their data. Data cleaning, preparation, and analysis will occur over four months, from April 13, 2027, to August 13, 2027. Manuscript writing, review, and author validations will occur over two months, from August 13, 2027, to October 13, 2027. We anticipate submitting the final manuscript in the fall/winter of 2027/2028.

5. Mobile Devices and Software

If required to provide more detailed information on the use of mobile devices and software, you may use the following language:

REDCap will be utilized for the secure collection of the de-identified study data. This may be used on any platform that can establish a secure connection with the Emory University REDCap database (e.g., smartphone, tablet, desktop, or laptop computer).

24. Appendix B: IRB Frequently Asked Questions

Q: How should we answer questions on funding for this project?

A: This project is currently not funded. It is appropriate to document "There is no funding for this project". We are in the process of seeking funding sources for this project. If a source of funding is acquired, we will provide an update to all OtoSurg members so that any future IRB and study documents will reflect this change.

Q: I am asked to list the number of individuals whose data/samples will be used. How many should I list?

A: This number will vary by institution. We recommend using an estimated number based on the typical number of pediatric tonsillectomy cases performed at your institution over a 60-day period. If providing an estimate from your institution's historical OR volume is not possible, you may use previous country cases in the literature to provide an evidence-based estimate. There is no minimum number of recorded patients per center or specific healthcare facility requirements.

Q: What data elements will be shared with the central REDCap database?

A: Data points include patient age, sex, anesthesia preoperative risk class, tonsillectomy indication, tonsillectomy technique, 30-day postoperative major complication (post-operative hemorrhage, hospital re-admission, need for repeat surgery), and postoperative 30-day mortality. In addition, data on participating sites will be collected, including the WHO health care facility level, country, WHO region, and country World Bank Income classification.

Q: Will the provider of the data/specimens remove the code before sending the data/specimens to the researcher?

A: Yes, the deidentified codes from the initial sites will be removed before uploading onto the central REDCap database.

Q: Is medical treatment provided as part of your research protocol? Or is any treatment described in the protocol being billed, electronically, to an insurance company?

A: No medical treatment is provided as part of the research protocol. No treatment described in the protocol is being billed, electronically, to an insurance company outside of the normal operating procedures of the facility at which the study is being performed.

Q: What are the data elements (i.e., HIPAA identifiers) that will be shared?

A: No identifiers will be shared with the REDCap database, as anonymized identifiers will be removed before data is uploaded. Data points include patient age, sex, anesthesia preoperative risk class, tonsillectomy indication, tonsillectomy technique, 30-day postoperative major complication (post-operative hemorrhage, hospital re-admission, need for repeat surgery), and postoperative 30-day mortality. In addition, data on participating sites will be collected, including the WHO healthcare facility level, country, WHO region, and country World Bank Income classification.

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