GLOBAL OHNS

EMORY UNIVERSITY

OTOSURG 1

TUTORIALS

#1. Data Abstraction → #2. Data Submission → #3. Data Validation

Welcome to the OtoSurg 1 written tutorials on **(1) data abstraction**, **(2) data submission**, and **(3) data validation**! These tutorials will guide you through the steps to obtain your data and complete each REDCap survey necessary for your participation in our collaborative study.

Our video tutorials are available here:

1. Data Abstraction	**2. Data Submission**	**3. Data Validation**

If you have any questions or concerns, please visit the OtoSurg website, watch our tutorial videos, or reach out to us at otosurgohns@gmail.com. We hope you find this series helpful, and we look forward to working with you throughout the study!

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Tutorial #1: Data Abstraction

1.0 Introduction

This tutorial covers data abstraction, or how to obtain and keep track of all data necessary to participate in this project. If you'd like to view this tutorial as a video, please click here.

1.1 Disclaimer

> **Only begin this process after you have received both IRB approval and your unique site ID (two-letter country code followed by four numbers) from the OtoSurg team.** If you have not yet received your site ID, please reach out to the OtoSurg leadership team.

1.2 Inclusion Criteria

Include all patients who are:

- Younger than 18 years and undergo a primary tonsillectomy during your site's designated study period.
- Tonsillectomy is defined as: the removal or ablation of any amount of palatine tonsil using any surgical method.
    - Includes unilateral and bilateral cases, and cases with concurrent procedures.

1.3 Data Collection Window

Select one consecutive **90-day study period** between October 13, 2026, and April 13, 2027.

- During the **first 60 days**, enroll every eligible patient.
- During the **final 30 days**, continue collecting postoperative outcome data on the patients you've already enrolled, but **do not enroll any new patients**.

Your team is responsible for putting site-specific strategies in place to identify and include every eligible patient during your enrollment period.

- This might mean checking the operating room schedule daily, reviewing surgical logs weekly, or using another method that fits your team and institution.
- **The goal is that no eligible patient is missed.**

1.4 Data linkage file setup: two options

Your team must **assign a de-identified study number to each enrolled patient** and maintain a **secure, local data linkage file** that connects each study number back to the patient's identity.

A couple reminders:

- After your data collection window closes, your team's Data Validator will need to see it and access it.
    - More information about that process can be found in Tutorial #3: Data Validation. For now, just keep in mind that this file will eventually need to be seen by one more person on your team.
- This file stays at your site. It is never sent to, or seen by, the central OtoSurg team.

You have two options for your data linkage file:

Option #1: Use your own. If your institution already has a system that works well, you're welcome to use/build your own linkage file.

Option #2: Use the OtoSurg template. If you'd prefer to use our template, go to the OtoSurg website, click "Resources for Partner Sites," scroll to the section "Data Collection Resources," and click on "OtoSurg Data Linkage File."

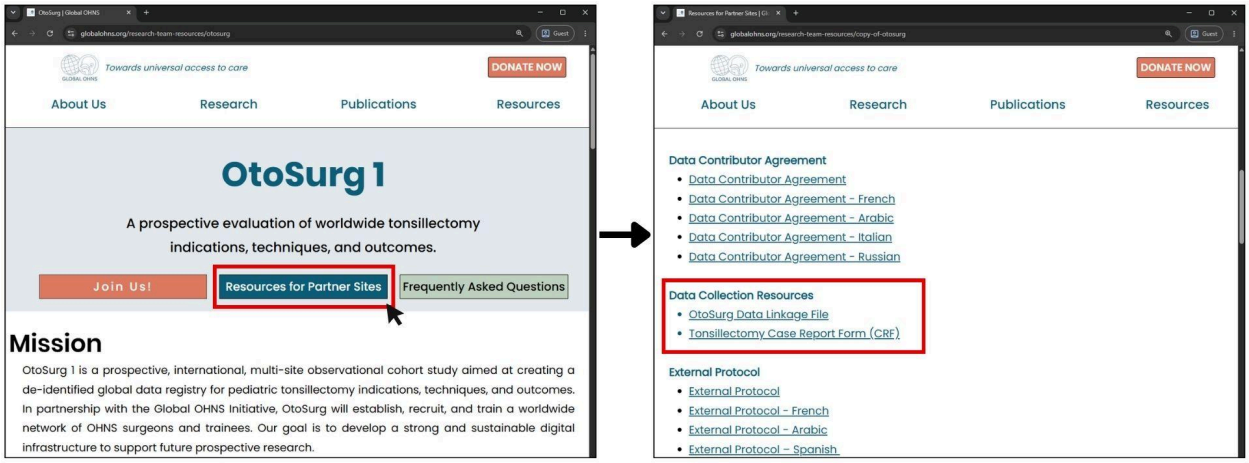


Figure 1. Navigation to the OtoSurg data linkage file.

1.5 OtoSurg data linkage file walkthrough

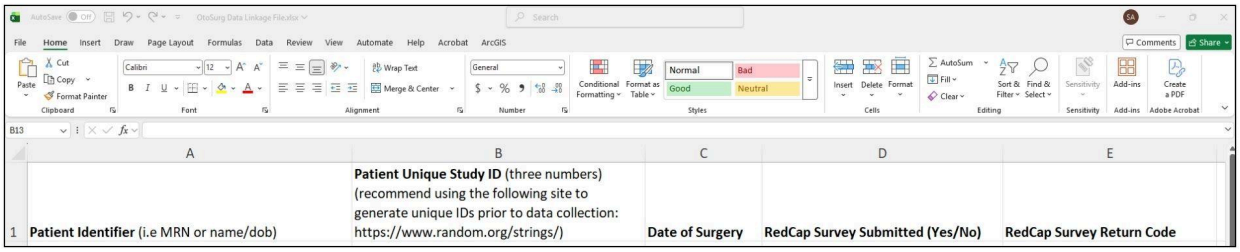


Figure 2. Preview of the OtoSurg data linkage file template.

The OtoSurg linkage template contains five columns.

A. **Column A: Patient identifier** - allows your team to quickly and reliably find that same patient's chart again later.
   - For electronic medical records, this is usually the patient's medical record number (MRN).
   - For paper charts, a last name plus date of birth is usually enough.
   - You're welcome to adjust this column to fit whatever identifier makes sense at your institution. The goal is to record the minimum amount of information needed to relocate each patient's chart.

B. **Column B: Patient Unique Study ID** - where you'll create and assign a unique, three-digit study ID number to each patient.
   - Because this number stands in for the patient's identity everywhere in the OtoSurg study, including when you submit the case through the REDCap survey, **it's very important to set this up correctly.**

- **Generate your full list of study ID numbers before you begin enrolling patients.** Don't make them up one at a time as you go. Pre-generating your list is what prevents your team from accidentally assigning the same number to two different patients.
    i. A free tool for this is at random.org/strings.
        1. Set the string length to 3 characters, choose numeric characters only, and enter how many separate ID numbers you'd like to generate at once.
        2. Click "Get Strings," and the site will produce a list of unique, non-repeating three-digit numbers you can paste directly into your linkage file.
    ii. Generate more numbers than you think you'll need. It costs nothing to have a few extra on your list, but running out partway through enrollment is a problem.
    iii. Once you've generated your random IDs, **copy-paste them back into column B in the data linkage file.**
- Remember that these **patient study ID's (3-digit numbers) are different from your site's study ID (two-letter country code with four numbers)**.

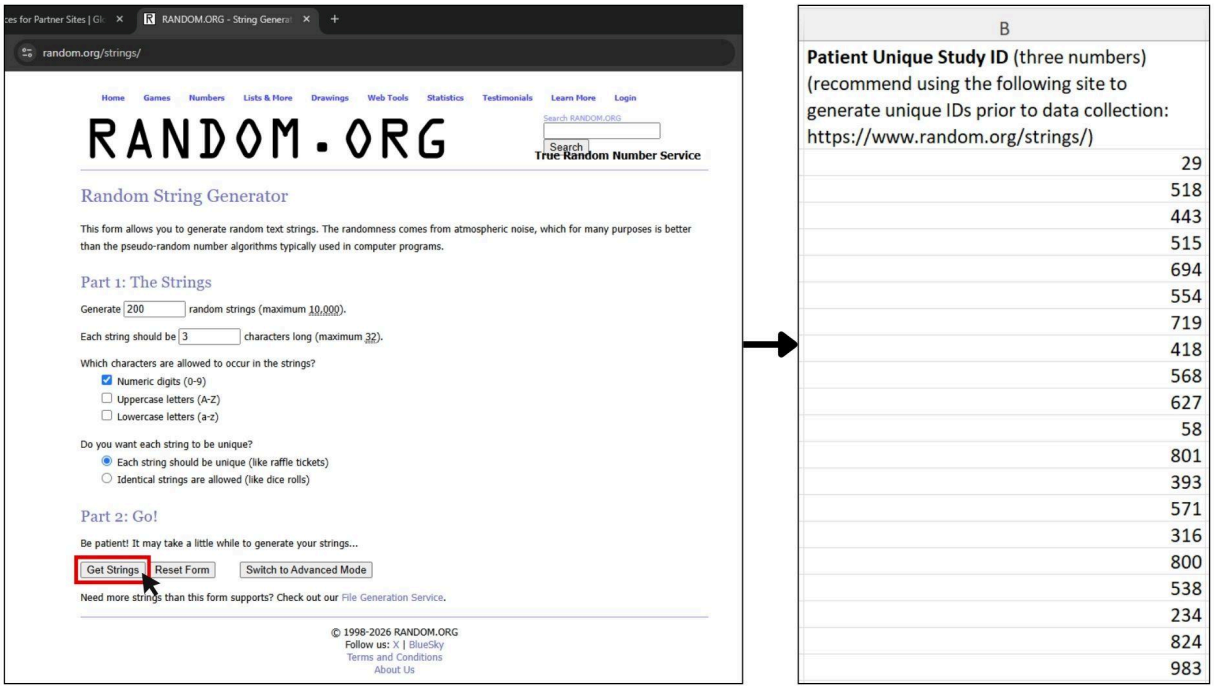


Figure 3. Use random.org/strings to generate study ID numbers and copy-paste them into Column B of the data linkage file template.

C. **Column C: Date of Surgery** - lets your team track how many days have passed since each patient's operation.
    - **Do not submit a case through RedCap until at least thirty days have passed since that patient's surgery**, so that you've had the full 30-day window to capture any postoperative complications.

D. **Column D: RedCap Survey Submitted** - mark whether or not a given patient's case has already been submitted through the RedCap survey.
    - **Keep this column current as you go**, to prevent your team from accidentally submitting the same case twice.
E. **Column E: RedCap Survey Return Code** - record the unique survey return code that REDCap gives you after each patient's data collection form is submitted.
    - **You must save this code for each patient**, as you will need it to access the patient's submitted survey in case you later catch any errors that you'd like to go back and fix.
    - For example, this is what your data linkage file might look like once you've submitted forms for your first three patients.

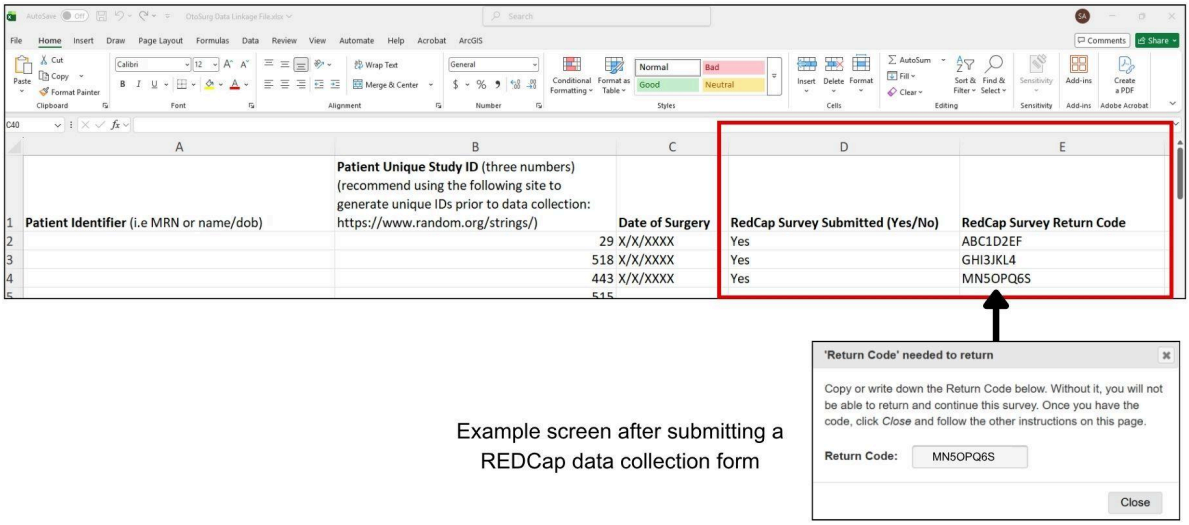


Figure 4. Always update the data linkage file with the REDCap survey status (submitted/not submitted) and corresponding survey return code for each patient.

1.6 Two options for data abstraction

There are two options for data abstraction, or how to actually pull the data out of the medical record so you're ready to complete the REDCap survey. Both are acceptable: choose whichever fits your team's workflow best.

- If your site prefers to use a completely different approach to pull and track data, that is also okay. We understand there is no one-size-fits-all given that every participating site is different, but the two options below are simple and effective.

1.61 Option 1: Abstract everything at once, thirty days after surgery

If all the required data points are already reliably documented in the medical record, you can use your linkage file to keep track of enrolled patients as they happen, and wait to do the actual data abstraction until you're ready to submit.

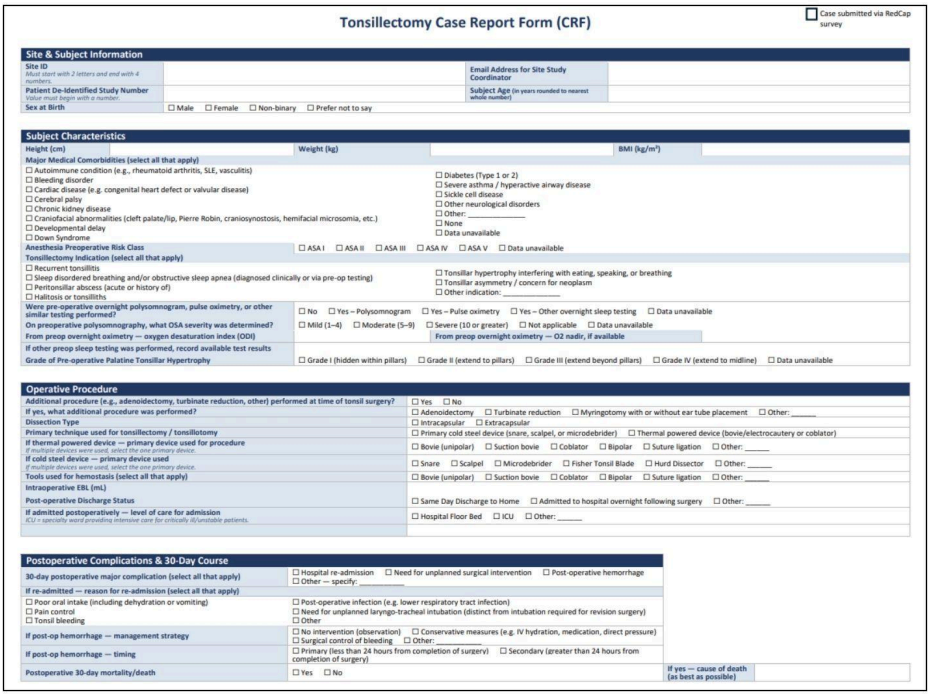
- Once thirty days have passed since a given patient's surgery, go back into that patient's chart, pull the information you need, and complete the REDCap survey in one sitting.
- Reminders:

    - As soon as you submit a case, go back to your linkage file and **mark that patient as submitted in the fourth column**, so you don't accidentally re-enter it later.
    - Remember to **add the survey return code** in case you need to go back and make any edits at a later date.
    - All cases from your site are **due within 90 days of your site's initial data collection start date**, so don't let cases sit too long before you circle back to them.

1.62 Option 2: Record each case in real time using the Case Report Form

We provide a Tonsillectomy Case Report Form on our website so you can record details for each patient right after their case, while the details are fresh, rather than waiting 30 days and relying on the chart alone.

- To access this form, go to the OtoSurg website, click "Resources for Partner Sites," scroll to "Data Collection Resources," and click on "Tonsillectomy Case Report Form." (See Figure 1.)
- The Case Report Form is a one-page worksheet that mirrors every question on the RedCap survey, organized into the same four sections you'll see in RedCap: Site and Subject Information, Subject Characteristics, Operative Procedure, and Postoperative Complications and 30-Day Course.
- Using this form is entirely optional, but it can be helpful if you're worried you won't be able to access a patient's chart again thirty days after surgery, or if you think some data elements might not end up clearly documented in the chart itself. In those situations, filling out the Case Report Form right away, while you still have firsthand knowledge of the case, gives you a reliable backup.
- Reminders:
    - **The Case Report Form itself is never submitted to OtoSurg.** It exists purely to help you complete the RedCap survey later.
        - You can print it and fill it out by hand, or complete it digitally — whatever works best for you.
    - **Always wait until at least 30 days after surgery to actually submit the case through REDCap**, since you still need that full window to capture postoperative complications.
    - Even if you are using the case report form, **keep the data linkage file updated in real time**. This option simply allows you to track more detailed data as well.



Tonsillectomy Case Report Form (CRF)

☐ Case submitted via RedCap survey

Site & Subject Information

Site ID *Must start with 2 letters and end with 4 numbers*		**Email Address for Site Study Coordinator**	
Patient De-Identified Study Number *Value must begin with a number.*		**Subject Age** (in years rounded to nearest whole number)	
Sex at Birth	☐ Male ☐ Female ☐ Non-binary ☐ Prefer not to say		

Subject Characteristics

Height (cm)		**Weight (kg)**	**BMI (kg/m²)**
Major Medical Comorbidities (select all that apply)			
☐ Autoimmune condition (e.g., rheumatoid arthritis, SLE, vasculitis) ☐ Bleeding disorder ☐ Cardiac disease (e.g. congenital heart defect or valvular disease) ☐ Cerebral palsy ☐ Chronic kidney disease ☐ Craniofacial abnormalities (cleft palate/lip, Pierre Robin, craniosynostosis, hemifacial microsomia, etc.) ☐ Developmental delay ☐ Down Syndrome		☐ Diabetes (Type 1 or 2) ☐ Severe asthma / hyperactive airway disease ☐ Sickle cell disease ☐ Other neurological disorders ☐ Other: _____ ☐ None ☐ Data unavailable	
Anesthesia Preoperative Risk Class	☐ ASA I ☐ ASA II ☐ ASA III ☐ ASA IV ☐ ASA V ☐ Data unavailable		
Tonsillectomy Indication (select all that apply)			
☐ Recurrent tonsillitis ☐ Sleep disordered breathing and/or obstructive sleep apnea (diagnosed clinically or via pre-op testing) ☐ Peritonsillar abscess (acute or history of) ☐ Halitosis or tonsilliths		☐ Tonsillar hypertrophy interfering with eating, speaking, or breathing ☐ Tonsillar asymmetry / concern for neoplasm ☐ Other indication: _____	
Were pre-operative overnight polysomnogram, pulse oximetry, or other similar testing performed?	☐ No ☐ Yes – Polysomnogram ☐ Yes – Pulse oximetry ☐ Yes – Other overnight sleep testing ☐ Data unavailable		
On preoperative polysomnography, what OSA severity was determined?	☐ Mild (1–4) ☐ Moderate (5–9) ☐ Severe (10 or greater) ☐ Not applicable ☐ Data unavailable		
From preop overnight oximetry — oxygen desaturation index (ODI)		**From preop overnight oximetry — O2 nadir, if available**	
If other preop sleep testing was performed, record available test results			
Grade of Pre-operative Palatine Tonsillar Hypertrophy	☐ Grade I (hidden within pillars) ☐ Grade II (extend to pillars) ☐ Grade III (extend beyond pillars) ☐ Grade IV (extend to midline) ☐ Data unavailable		

Operative Procedure

Additional procedure (e.g., adenoidectomy, turbinate reduction, other) performed at time of tonsil surgery?	☐ Yes ☐ No
If yes, what additional procedure was performed?	☐ Adenoidectomy ☐ Turbinate reduction ☐ Myringotomy with or without ear tube placement ☐ Other: _____
Dissection Type	☐ Intracapsular ☐ Extracapsular
Primary technique used for tonsillectomy / tonsillotomy	☐ Primary cold steel device (snare, scalpel, or microdebrider) ☐ Thermal powered device (bovie/electrocautery or coblator)
If thermal powered device — primary device used for procedure *If multiple devices were used, select the one primary device.*	☐ Bovie (unipolar) ☐ Suction bovie ☐ Coblator ☐ Bipolar ☐ Suture ligation ☐ Other: _____
If cold steel device — primary device used *If multiple devices were used, select the one primary device.*	☐ Snare ☐ Scalpel ☐ Microdebrider ☐ Fisher Tonsil Blade ☐ Hurd Dissector ☐ Other: _____
Tools used for hemostasis (select all that apply)	☐ Bovie (unipolar) ☐ Suction bovie ☐ Coblator ☐ Bipolar ☐ Suture ligation ☐ Other: _____
Intraoperative EBL (mL)	
Post-operative Discharge Status	☐ Same Day Discharge to Home ☐ Admitted to hospital overnight following surgery ☐ Other: _____
If admitted postoperatively — level of care for admission *ICU = specialty ward providing intensive care for critically ill/unstable patients.*	☐ Hospital Floor Bed ☐ ICU ☐ Other: _____

Postoperative Complications & 30-Day Course

30-day postoperative major complication (select all that apply)	☐ Hospital re-admission ☐ Need for unplanned surgical intervention ☐ Post-operative hemorrhage ☐ Other — specify: _____		
If re-admitted — reason for re-admission (select all that apply)			
☐ Poor oral intake (including dehydration or vomiting) ☐ Pain control ☐ Tonsil bleeding	☐ Post-operative infection (e.g. lower respiratory tract infection) ☐ Need for unplanned laryngo-tracheal intubation (distinct from intubation required for revision surgery) ☐ Other		
If post-op hemorrhage — management strategy	☐ No intervention (observation) ☐ Conservative measures (e.g. IV hydration, medication, direct pressure) ☐ Surgical control of bleeding ☐ Other: _____		
If post-op hemorrhage — timing	☐ Primary (less than 24 hours from completion of surgery) ☐ Secondary (greater than 24 hours from completion of surgery)		
Postoperative 30-day mortality/death	☐ Yes ☐ No	**If yes — cause of death (as best as possible)**	

Figure 5. The tonsillectomy case report form (CRF) provided by OtoSurg 1.

1.7 Data Abstraction Conclusion

The two options listed above aren't the only way to approach data abstraction - if your team has (or finds) a different local workflow that works better for you, that's completely fine.

- What matters is that every enrolled patient's data is captured accurately and completely, and that no case is submitted before its full 30-day postoperative window has closed.
- Once your data is successfully abstracted and you're ready to submit, the next step is filling out the REDCap case survey for each patient (covered in **Tutorial #2: Data Submission**).

Tutorial #2: Data Submission

2.0 Introduction

This tutorial covers data submission, which involves filling out a separate REDCap survey for each included study patient, and takes place after data abstraction. If you'd like to view this tutorial as a video, please click here.

2.1 Disclaimers

Before submitting your REDCap surveys, please keep the following items in mind:

- You must submit each patient's REDCap survey **no earlier than 30 days after their surgery date** and **no later than the end of your 90-day study period**.
- A separate survey must be submitted for each patient included in your study.
  - We strongly encourage completing each survey in one sitting to avoid losing your progress.
- Be sure to refer to your data linkage file often and keep it up-to-date so that you're always aware of which patients are ready to be submitted and which patients have already been submitted.

2.2 REDCap Pediatric Tonsillectomy Case Survey Walkthrough

2.20 Accessing the form

- To get to the REDCap data submission survey, go to the OtoSurg website, click "Resources for Partner Sites," and scroll down to the section "REDCap links." Click on "Tonsillectomy Case Submission Form."

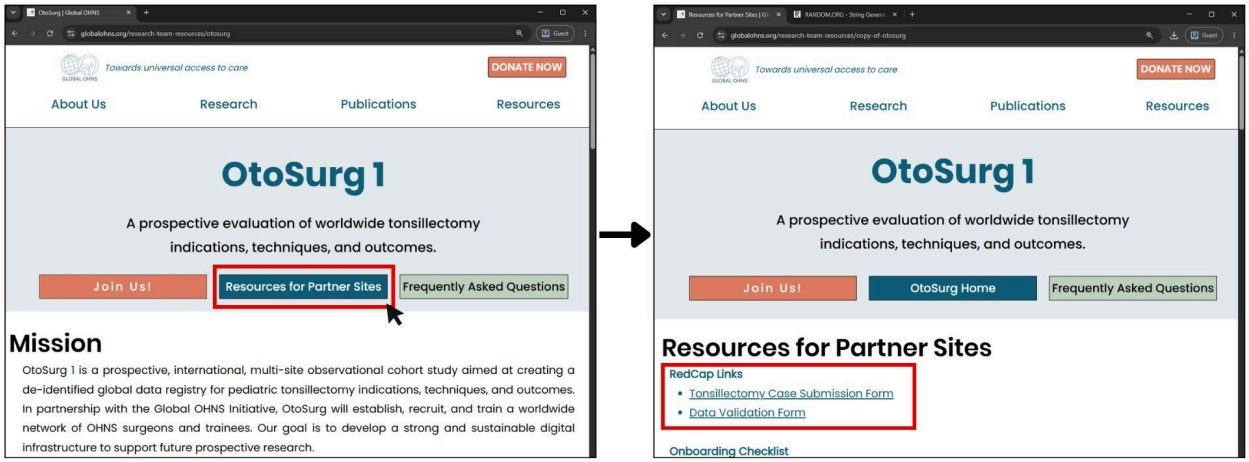


Figure 6. Navigate to the Tonsillectomy Case Submission form.

- Input the survey password, which you will receive in an email from the OtoSurg team.
  - Keep this password for your records and **do not share it** with any individuals outside your team.
  - After inputting the password, click away from the text box so that the rest of the survey questions can populate.

2.21 Study site information

- Site ID: input your unique site ID, a two-letter country code followed by four numbers.
    - Remember that your site ID is different from the patient's 3-digit study ID.
- Email address for site study coordinator: provide your coordinator's email.

2.22 Subject demographics

- Patient De-identified Study Number: input the unique, deidentified code for the specific study subject. This value must be a number.
- Sex at birth: select one value from female, male, non-binary, or prefer not to say.
- Subject age: input the patient's age at the time of the procedure, rounded to the nearest whole year (ex. 9).

2.23 Subject characteristics

- Subject height: record in centimeters, to one decimal place.
- Subject weight: record in kilograms, to one decimal place.
- Body mass index (BMI): the survey will automatically calculate the patient's BMI.
- Major medical comorbidities (health conditions): select all major medical comorbidities the patient has.
    - Check "other" if they have comorbidities not covered by any of the listed categories.
    - Check "none" if they have no major comorbidities.
    - Check "data unavailable" only if data is not accessible or is missing. The same applies to subsequent questions.
- Anesthesia preoperative risk class (ASA): select which ASA class the patient belongs to.
    - Definitions of each ASA classification are provided in the survey.
- Tonsillectomy indication: select all tonsillectomy indications that apply.
    - If indicated only for symptoms of snoring, only select the SDB/OSA option.
- Pre-operative testing: indicate all tests that were performed before surgery, such as polysomnogram, pulse oximetry, or other.
    - Check "data unavailable" if this data was collected but is not accessible or is missing.
    - Check "no" if this data was never collected.
- Grade of pre-operative palatine tonsillar hypertrophy: select the option that describes the patient's pre-operative tonsillar hypertrophy. Definitions of each grade are provided.

2.24 Subject characteristics

- Additional procedure performed at the time of tonsil surgery: select Yes or No.
- Dissection type: indicate whether an intracapsular (partial/tonsillotomy) or an extracapsular (total) procedure was performed.
- Primary technique: select the single best answer that describes the procedure, either primary cold steel or thermal-powered.
- Hemostatic tools: select all that apply from the listed options.
    - If you select "other," provide more details through an open text field.
- Estimated blood loss: provide a number to the nearest mL.

- Post-operative discharge status: select the most appropriate option from the dropdown field (same-day discharge, admitted to hospital overnight following surgery, other).

2.25 Postoperative complications and 30 day course

Reminder: only submit this form **AFTER at least 30 days post-surgery** so that you have captured the relevant window for post-operative complications.

- 30-day postoperative major complications: select all options that apply.
    - Check “none” if no post-op complications occurred.
    - Additional questions may populate depending on the option(s) selected. Be prepared to provide further information when necessary.
- Postoperative 3-day mortality/death: select Yes or No.
    - If “Yes” is selected, describe the postoperative cause of death (as best as possible).

2.26 Save and return

- **We strongly encourage you to fill out each survey in one sitting**, but if you need to stop and come back, click “Save & Return” at the bottom of the form.
- Save the unique return code for that case so you can finish that patient’s survey later.

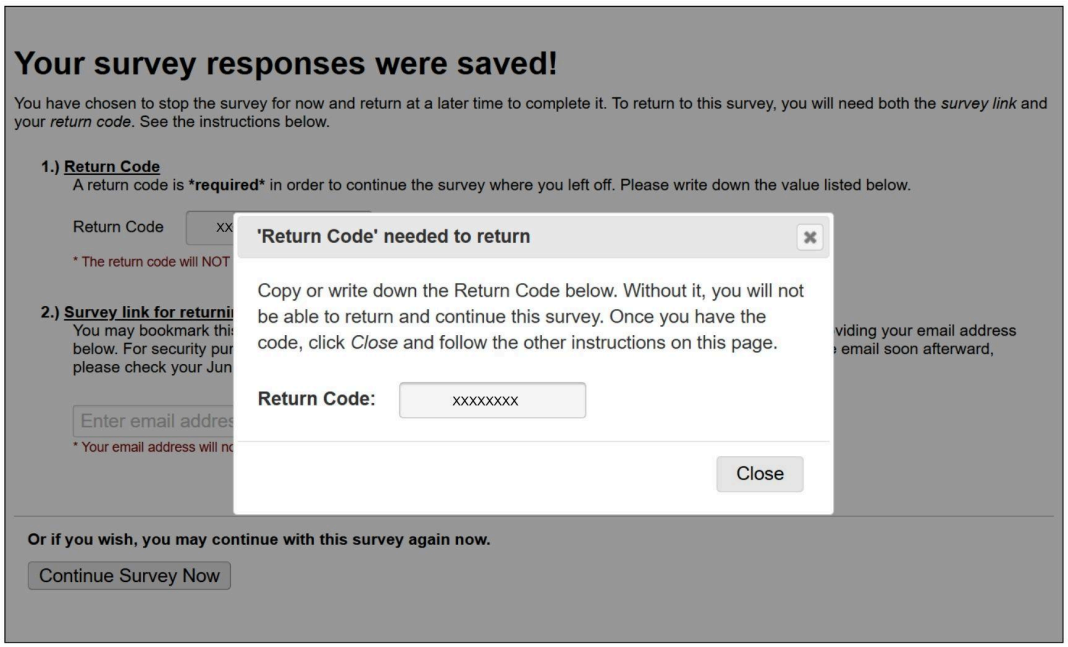


Figure 7. Save the unique return code for any cases that you haven’t finished submitting.

2.27 Final submission

- **Always double-check your answers,** then click “Submit.”
- Keep the unique return code provided by REDCap.
- As soon as you’ve submitted a case, immediately go back to the linkage file, **mark the patient as submitted**, and copy-paste the return code. (See Figure 4.)
- Repeat this process for all patients in the cohort.

2.3 Data Submission Conclusion

To summarize, a **separate survey** must be submitted for each patient included in your study.

- We strongly suggest completing each survey in one sitting.
- In your data linkage file, **always track which patients' forms you've submitted and record the corresponding unique return codes**.
- All surveys must be submitted **no earlier than 30 days after surgery** and **no later than the end of your site's 90-day study period**.

Once you've submitted all your forms, the final step is data validation (**Tutorial #3: Data Validation**).

Tutorial #3: Data Validation

3.0 Introduction

This tutorial covers data validation: the final step of your site's participation in this study. As a reminder, each site will designate a team member as the data validator, who completes this part of the process **independently** from the data collectors on your team. This means that **the data collectors will not be able to view the REDCap surveys submitted by the data validator**. If you'd like to view this tutorial as a video, please click here.

3.1 Data Validator: Access and Responsibilities

To perform data validation, the validator needs access to both the **deidentified study data** and the **local data linkage file** created by the rest of the team.

- Using this information, the validator will conduct retrospective chart review to evaluate the accuracy and completeness of the recorded data, and then determine if patients had postoperative follow-up.

The data validator thus has two responsibilities:

1. Independently perform **case ascertainment,**
2. **Review** five randomly selected cases, then submit a separate data validation survey for each one.

3.2 Responsibility #1: Case Ascertainment

For case ascertainment, start by checking whether informed consent is required for participation at your site.

- If informed consent is required at your site, case ascertainment is not possible. Skip ahead to case selection.
- If informed consent is not required at your site, the validator must **independently keep their own running count of every tonsillectomy case eligible for inclusion during the site's data collection window**.
    - This count should be kept separately from, and without relying on, the count kept by the rest of the enrollment team.
    - This information can be gathered prospectively or retrospectively, depending on what is most practical for your site's workflow.
    - At the end of the data collection window, this independently-kept count will be compared against the total number of cases the team actually enrolled. A close match confirms that your site captured its full eligible population.

One important disclaimer is that sites missing data for over 20% of patients **may** be excluded from authorship.

- This will be determined on a case-by-case basis. Every effort will be made to include all sites that make a strong and genuine effort to include all eligible patients in their study.
- This policy is likely only to be enacted if there are significant or concerning discrepancies.

3.3 Responsibility #2: Independent Case Review

Once all of the site's cases have been submitted through REDCap, the validator will obtain a copy of the site's data linkage file from the data collectors and **select five cases at random to review**.

- Most importantly, these five cases must be chosen **at random**, not based on convenience or which charts happen to be easiest to pull.
- If your site submitted fewer than five cases in total, the validator should review all of the cases you have.

To randomly select cases, we recommend a free random number generator, such as the one at random.org/integers.

- Enter 5 as the number of random integers you need, set the minimum to 1, the maximum to the total number of cases your site submitted, and generate the list.
- The resulting 5 numbers correspond to the five cases the validator will independently review, based on their order in the linkage file.

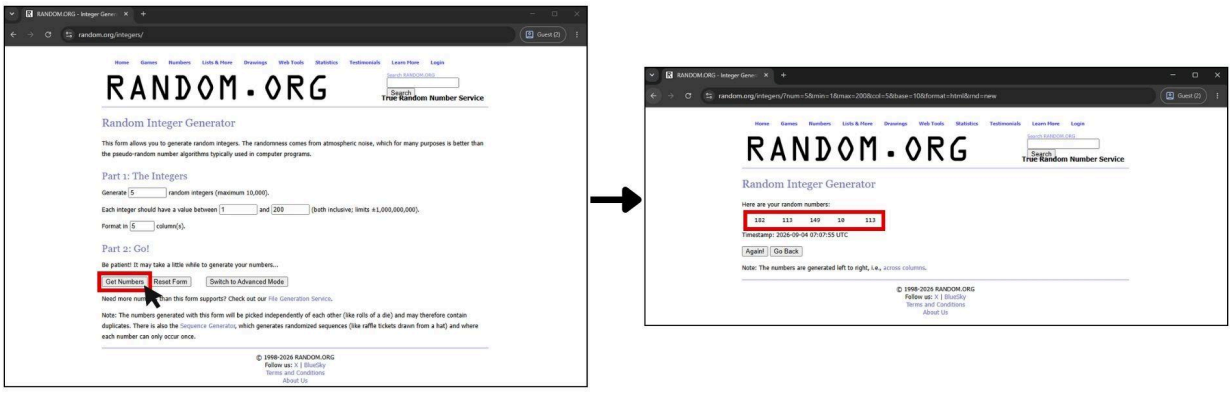


Figure 8. Use random.org/integers to randomly select cases for review.

After the five cases have been randomly selected, the validator will abstract the necessary data for each of those patients directly from the medical record, **independently** from whatever the data collector(s) recorded initially, and use that data to submit a separate validation survey for each case.

- To get to the REDCap data validation survey, go to the OtoSurg website, click "Resources for Partner Sites," scroll to the section "REDCap links," and click on "Data Validation Form." (See Figure 6.)

3.31 Starting the validation survey

Just like in the data submission form, start by inputting the survey password, your unique site ID (2 letters and 4 numbers), and your site study coordinator email.

3.32 Research requirement (IRB)

- Did your local IRB require informed consent: select "Yes" or "No."
    - As mentioned in Section 3.2, if informed consent was required, select "Yes" and move on to the next section.

- If informed consent was not required, select “No” and write the validator’s independent count of the total number of cases that were eligible for inclusion during your site's data collection window.

3.33 Main sections - refer to Tutorial #2: Data Submission

The next sections are exactly the same as in the data submission form: subject demographics, subject characteristics, operative procedure, and post-operative complications and 30-day course. If you have any questions about these sections, please refer to our previous tutorial on Data Submission.

3.34 Follow-up

- Postoperative evaluation within 30 days of tonsillectomy, either in-person or by telephone/virtual visit: select “Yes” or “No.”

3.35 Submit

- Always double-check your answers to the data validation survey before submitting. **You cannot go back and change your responses after submitting.**
- Repeat the process for all 5 cases randomly selected for review.

3.4 Data Validation Conclusion

To summarize, the data validator must complete these processes **independently** from the data collectors and the rest of the study team.

- Cases for review must be **randomly selected**.
- Always double-check your answers.

After you’ve submitted your cases for validation, a member of the central OtoSurg team will verify them against the original submitted data for accuracy.

3.5 Questions or concerns

This concludes our series on data abstraction, data submission, and data validation. Thank you for reading these tutorials and contributing to our collaborative study!

If you have any questions or concerns, please visit the OtoSurg website, watch our tutorial videos, or reach out to us at otosurgohns@gmail.com. We hope you found this series helpful, and we look forward to working with you throughout the study.

Thanks again, and best of luck!