**Delete all sections in Blue or Red prior to submission to the IRB**

**REGISTRY/REPOSITORY TEMPLATE**

**Sections that are not applicable can be deleted.**

|  |  |
| --- | --- |
| Title: | **Complete Title** |
| Protocol No: | **XXXX-XXX** |
| Protocol Date: |  |
| Amendment 1 Date:  | Amendment 4 Date:  |
| Amendment 2 Date: | Amendment 5 Date: |
| Amendment 3 Date: | Amendment 6 Date: |
| **Funder** (if applicable)NameFunder NameAddressCity, State, ZipCountry |
| **Study Principal Investigator** Hospital/University/FunderOffice AddressCity, ST, ZIPPhone XXX-XXX-XXXXemail: XXXXX@XXX.XXX |

**Include a signature page for Multi-center research studies**

**SITE INVESTIGATORS SIGNATURE PAGE**

|  |  |
| --- | --- |
| Protocol Title |  |
| Short Title |  |
| Lead InvestigatorAcademic Affiliation |  |
| Protocol Version |  |
| Version Date |  |

I conﬁrm that I have read this protocol, I understand it, and I will conduct the study according to the protocol. I will also work consistently with the ethical principles that have their origin in the Declaration of Helsinki and will adhere to the Ethical and Regulatory Considerations as stated. I conﬁrm that if I or any of my staﬀ are members of the Institutional Review Board, we will abstain from voting on this protocol, its future renewals, and its future amendments.

|  |  |
| --- | --- |
| Site Principal Investigator Name |  |
| Site Principal Investigator Signature |  |
| Date: |  |

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Abbreviations and Definitions of Terms

|  |  |  |
| --- | --- | --- |
|  |  | Insert and delete terms as relevant |
| AE |  | Adverse event |
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Abstract

Use JAMA format (http://jama.ama-assn.org/misc/ifora.dtl#Abstracts). Limit to 150 – 200 word abstract, written for lay members. This abstract is used in the IRB database and in the minutes of meetings.

Context: (Background)

Include 1 - 3 sentences about the clinical importance of the condition and the importance of the research question.

Objectives: (primary and important secondary objectives)

State the precise objective (e.g. The purpose of the registry/repository is to provide a mechanism to store data and/or specimens to support the conduct of future research about XXXXXXXXXX).

Study Design:

Basic design: Data registry and/or Biospecimen repository. Organizational Structure. Potential Future Use

Setting/Participants:

The setting, including location (referral or community center) and level of care (inpatient or outpatient). The number of sites. The number and description of participants including key eligibility criteria

Data/Specimen Collection Procedures and Frequency:

EXAMPLE: Table 1: Schedule of Study Procedures

|  |  |  |
| --- | --- | --- |
| **Study Phase** | **Visit 1** | **Follow Up Visits**  |
| **Visit Number** |  | **1** | **2** | **3** | **4-7** |
| Study Days (e.g.) |  | 3 months | 6 months | 12 months | Annually (2 -5 years) |
| Informed Consent/Assent | X |  |  |  |  |
| Review Inclusion/Exclusion Criteria | X |  |  |  |  |
| Demographics/Medical History/Questionnaire | X |  |  |  |  |
| Blood collection | X | X | X | X | X |
| Urine collection | X |  |  | X | X |
| Skin biopsy | X |  |  |  |  |
| Saliva/buccal swab | X |  |  |  |  |
| Left-over specimen from clinical care procedures (e.g. bone marrow aspirate, CSF, tumor tissue)  | X | X | X | X | X |
| Extra specimens at the time of a clinical procedure (e.g. biopsy during endoscopy) | X |  |  | X | X |

This table is an example of a schedule of procedures. If there is only one study visit for the Registry/Repository, then a Table may not be necessary. The table should be based on the actual procedures in the protocol.

# Background Information and Rationale

This section should be no more than 3 – 5 pages. Refer the reader to the attached literature references for more detailed information.

## Introduction

Provide background information to orient the reviewer (who may not be familiar with your specialty) to the issue under investigation. Provide a brief overview of the following:

Rationale for developing the registry/repository including information about the disease or condition, the target population and the unmet need and value of the desired information/specimens for future research.

Potential future uses of the repository/registry

Collaborating investigators or group(s)/other sites

Funding sources

Organizational structure

## Compliance Statement

This study will be conducted in full accordance all applicable Children’s Hospital of Philadelphia Research Policies and Procedures and all applicable Federal and state laws and regulations including 45 CFR 46, and the HIPAA Privacy Rule. Any episode of noncompliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent and assent (unless a waiver is granted), and will report unexpected problems in accordance with The Children’s Hospital of Philadelphia IRB Policies and Procedures and all federal requirements. Collection, recording, and reporting of data will be accurate and will ensure the privacy, health, and welfare of research subjects during and after the study.

## Relevant Literature and Data

Provide a concise summary, identifying issues that this study will address. Point out any sources that would be especially useful in providing an overview of the subject.

# Study Objectives

*State the objectives of the registry/repository.*

The purpose of the registry/repository is to provide a mechanism to store data and/or specimens to support the conduct of future research about XXXXXXXXXX.

## Primary Objective (or Aim)

The primary objective of this study is to provide a mechanism to store the following information about subjects with DISEASE or CONDITION. This can include storage of data for subjects who will serve as controls for such research as well, e.g., genome wide association studies.

# Investigational plan

## General Schema of Registry/Repository Design

Provide an overview of registry/repository including a general description of the participating sites, the nature of the data and specimens and the mechanisms for protections.

**NOTE:** **If there are specific study objectives beyond collecting data/specimens to support future research, then the study should be submitted as either a clinical trial or an observational study with a biorepository to store data/specimens.** A registry/repository using this protocol template is intended for FUTURE research, and not to address immediate research questions.

### Total Number & Description of Study Sites/Total Number of Subjects Projected (for multi-center research where CHOP will host the repository)

The study will be conducted at approximately XX investigative sites in the United States and XXXX.

A listing of the various sites that will be providing data/biospecimens to the registry/repository. (**NOTE:** CHOP and all of its satellite locations are considered one site). Information should include the policies and methods governing how the registry/repository will ensure that each investigator is qualified, that the local IRB meets the local requirements for registration for US-based sites, and that the IRB/ethics board approval is issued before the site begins participation in the human subjects research. The latter can, e.g., be ensured by requiring a copy of the IRB/ethics board approval letter and subsequent continuing approval letters (as applicable).

Recruitment will stop when approximately XXX subjects are enrolled. The investigator anticipates enrolling XXX subjects per year.

### Overview of the Data/Biospecimen Collection

Provide a high-level overview of the methods that will be employed for obtaining the data/biospecimens (sources could include e.g., database, existing specimens sources, research procedures such as blood draws or biopsies, etc.). The specifics will go in Sections 4.

## Study Duration, Enrollment and Number of Sites

### Duration of Subject Study Participation

This section refers to the duration of the subject’s participation, not the duration of the study from the investigators’ standpoint.

## Study Population

Even if the study is retrospective (i.e. all data and specimens exist at the time of IRB submission), the study population must still be defined using inclusion and exclusion criteria. If there is more than one population (e.g. index cases and parents), then there should be separate inclusion/exclusion criteria for each population.

### Inclusion Criteria for Cases (examples)

1. Males or females age 0 to 16 years at the time of treatment
2. Tonsillectomy (with or without adenoidectomy) between 1/1/1995 and 12/31/2005
3. Completed operative note
4. Additional criteria as required
5. Parental/guardian permission (informed consent) and if appropriate, child assent. (Include ONLY if waiver of informed consent is not appropriate).

### Exclusion Criteria for Cases (examples)

1. Previous tonsillectomy, here or elsewhere
2. Named craniofacial syndrome

### Inclusion Criteria - Controls/Parents/Siblings (examples)

1. Parents or siblings of index cases
2. Parental/guardian permission (informed consent) and if appropriate, child assent. (Include ONLY if waiver of informed consent is not appropriate)

### Exclusion Criteria - Controls/Parents/Siblings (examples)

1. Adoptive parent or non-biologically related sibling
2. Age 6 – 60 years

# Study Procedures

This section should list the data elements and biospecimens that will be collected as part of the registry/repository as well as the timing and frequency of the data/specimen collection (Visit Schedule). Some Biorepositories collect data/specimens at a single point in time while many continue to collect data and/or specimens over extended periods of time.

This section should list the procedures. The Table of Study Procedures on page vii should mimic the visit-by-visit listing of procedures. **Protocol Writing Tip**: Section 4 lists what will be done and Section 5 describes how it will be done.

## Screening Visit

List the timing and all of the procedures to be performed at the screening visit used to establish eligibility and to obtain informed consent. This can be a simple bullet list. If there is no screening visit, delete this sub-section.

The IRB may approve screening procedures without obtaining the prior informed consent of the prospective subject or the subject’s legally authorized representative only if the solicited information is **limited to the minimum necessary for screening/determining eligibility** for the main study AND if these procedures are limited to: (a) obtaining information through oral or written communication with the prospective subject or legally authorized representative, or (b) obtaining identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens. **NOTE:** If the information or biospecimens used for the purpose of screening, recruiting, or determining the eligibility of subjects include protected health information (PHI), HIPAA applies and HIPAA Authorization may still need to be obtained prior to conducting these screening activities. See [Recruitment vs Screening](https://irb.research.chop.edu/recruitment-vs-screening) for more information.

* Informed Consent
* Medical Record Review
* Questionnaire

## Data and Specimen Collection

Provide a general overview of this portion of the study. This might involve a single study visit or could include a collection of data/specimens at intervals over a prolonged period of time.

Below, provide a detailed description of each study visit - including all procedures. This is usually included as a simple bullet list including e.g. all the various specimens to be collected at that visit. Only list procedures that will be done for the research. For example, if weight, height and vital signs will come from the clinical care visit, then they would fall under Medical Record Review.

The study team members should be able to quickly review the list of procedures at each visit in order to correctly execute the study.

### Visit 1

Specimen collection for future research, e.g. blood/saliva/tissue/skin biopsy. **Protocol Writing Tip**: The details of how the specimens will be collected should be located in Section 5.

Medical Record Review

### Visit 2

Detailed description of study visit including all procedures using the same format as above.

### Visit 3

Detailed description of study visit including all procedures – listed like above examples.

### Visit 4, etc.

Detailed description of study visit including all procedures – listed like above examples.

## Unscheduled Visits

(if applicable) Description of how unscheduled visits will be handled (e.g. if subject is seen in the ED outside a scheduled visit, would e.g. left-over samples be collected).

## Subject Completion/Withdrawal

Criteria for withdrawal of subjects. Example: *Subjects may withdraw from the study at any time without prejudice to their care. They may also be discontinued from the study at the discretion of the Investigator for lack of adherence to study visit schedules, AEs, or due to REASON (list). The Investigator or the funder (if applicable) may also withdraw subjects who violate the study plan, or to protect the subject for reasons of safety or for administrative reasons. It will be documented whether or not each subject completes the study.*

# Study Evaluations and Measurements

## Medical/Phenotype Data Collection Procedures

Explain where the data will come from. Will it come from medical or other research records, or will there be additional procedures conducted solely for this study, such as medical health history interview, questionnaires, surveys, etc., that are not part of routine clinical or existing research protocol.

For example, “EPIC will be queried for demographic information, admission dates and discharge diagnoses. Surgical approach will be abstracted from the Operative Note. Indications and recovery information will be obtained from the office chart.”

Who will perform the data collection? If the data is abstracted from electronic records, who will perform this operation and will all PHI be stripped from the dataset prior to inclusion in the Registry/Repository? (Is an honest broker or other site providing the investigators with data that is not readily identifiable or is identifiable data being collected.)

The listings and sections below are examples. The protocol should be revised/written to match the intended procedures.

### Medical Record Review / PHI Elements Collected

Include a listing of the variables that will be abstracted from the medical chart (paper or electronic), or any personally identifiable health information (any of the 18 HIPAA identifiers that will be recorded as part of the research) that will be collected. The elements that will be maintained at the site by the collector should be listed separately from the PHI elements that will be sent to the registry/repository.

* Name
* MRN
* Date of birth
* Weight

### Questionnaires, Surveys or Interview

Provide a short paragraph describing each survey instrument. Psychological or other measurement scales that will be used should be described. Those that have been validated and that are on the IRB's listing of [Validated Instruments](https://irb.research.chop.edu/validated-instruments) may simply be referenced. Those that are not on the list should be included in the appendix or uploaded into eIRB.

### Other Evaluations, Measures

Describe other rating scales, tests, psychological tools, etc., if any. If non are performed for research purposes, delete this sub-section.

## Biospecimens

Provide a brief overview of the specimens to be collected. Is this leftover tissue from clinical care procedures, extra samples collected at the time of a clinical procedure (e.g. extra CSF at the time of a clinically indicated LP), tissue obtained from another research study, or will it be obtained purely for this research study? Will it be collected as the same time as clinical or other research samples? If skin biopsies are conducted solely for research procedures, how big is it, will sutures be required?

### Specimen and Collection Procedures for First Specimen

For each type of specimen that will be collected, provide a description of the collection procedures, the amount to be taken (e.g. 5 ml of blood), and the schedule of timing of collection if the specimen will be collected more than once.

Include the IRB study number(s) for which this Registry/Repository will store specimens, or if this is a stand-alone repository, provide a summary of the investigators/sites who will be providing the data/biospecimens.

For CHOP-only registry/repositories, an Appendix should be included that lists each data element that will be obtained from each database source.

### Specimen and Collection Procedures for Second Specimen (add additional sections as required)

For each type of specimen that will be collected provide a description of the collection procedures, the amount to be taken (e.g. 5 ml of blood), and the schedule of timing of collection if the specimen will be collected more than once.

Include the IRB study number(s) for which this Registry/Repository will store specimens, or if this is a stand-alone repository, provide a summary of the investigators/sites who will be providing the data/biospecimens.

For CHOP-only registry/repositories, an Appendix should be included that lists each data elements that will be obtained from each database source.

### Specimens Rolled Over from Other Studies

If specimens previously collected for another study are to be included (rolled over) in this study, indicate the IRB study number(s), whether the consent form for the initial study includes provisions to allow future research, and if so, confirm that only subjects who agreed to future research will be included in this study.

If such samples were collected at another institution and are now transferred, indicate that they are transferred in accordance with institutional requirements/contracts/transfer agreements.

If no specimens from another study will be included (rolled over) in this study, delete this sub-section.

### De-identified Specimens or Specimens from Decedents

If de-identified specimens will be included in the repository, add the following (if not, delete this sub-section):

The repository will also include data/samples from individuals, whose identity the investigators cannot readily ascertain (e.g. de-identified, or coded samples from a collaborator). If the data/samples are being provided by a data registry, biospecimen repository or other data source, the investigators will maintain documentation that either of the following is in place: (1) policies and procedures that prevent the release of identifiers; or (2) an agreement in place between the data source and the investigator stating that no identifiers will be released under any circumstances. Research on samples/data which are not readily identifiable does not constitute human subjects research. Therefore, the individuals whose not readily identifiable data/samples are included in this research will not be included in the enrollment numbers for this study.

# Registry/repository ADMINISTRATION

A Registry/Repository is organized to facilitate future use, so this information is critical for understanding the human subjects issues. To be maximally beneficial for future research, policies and procedures need to be in place describing how the Registry/Repository will operate, how it will release data/specimens, and how the data/specimens will be identified when released.

## Study Organization

Describe the overall organization and structure of the Registry/Repository.

Describe the Policies and Procedures (written) for granting access for future use.

Describe how decisions will be made for granting access to investigators for future uses of the materials in the Registry/Repository? How will the Registry/Repository make these determinations?

Describe procedures and policies for distributing data/specimens for future research. There are usually three conditions for release of data/specimens: (1) without identifiers (no IRB approval needed and no HIPAA authorization or waiver), (2) with a limited data set (usually without IRB approval but with a Data Use Agreement executed by recipient and Registry/Repository), or (3) with identifiers (requires IRB approval or determination of exemption and may require waiver of consent and HIPAA authorization).

## Data Collection and Management

Describe the system for maintaining primary records (source documents), case report forms, and for entering the data into any computerized systems. Address the following:

### Computer Systems

Describe the computer systems, facilities and equipment. Describe the backup plan and recovery plans. Describe the password protection and data encryption systems that will be in place. What are the plans for restricting and controlling access to the research data?

### Confidentiality of Subjects:

Describe the methods for ensuring the privacy of subjects and the confidentiality of their data/biospecimens.

Describe the coding scheme for data/biospecimens. Who will generate the code? Will the code include any elements of PHI (e.g., initials or dates)? How will the data be linked back to subjects? Will the collecting site retain the link to PHI or will the Registry/Repository possess the PHI and have access to the link between data/biospecimens and subjects?

If PHI will be sent to the Registry/Repository, it must be listed in the informed consent document and this must be justified.

Include descriptions or attach copies of Policies or Procedures related to use or disclosure of PHI for research purposes. If data/biospecimens will be anonymized (all PHI removed), describe how that will be done and by whom, as well as the methods that will be used to anonymize or de-identify data/biospecimens prior to future use.

#### Certificate of Confidentiality

If a certificate of confidentiality (CoC) will be obtained, then that information should be provided. **NOTE:** NIH-funded studies are [automatically deemed](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html) to have a CoC. When a CoC is in place, confirm that the same CoC protections will be applied to the usage of this study’s data for any future studies (for additional information on CoCs, please see the IRB's website: <https://irb.research.chop.edu/certificates-confidentiality>) and that the investigator will alert any data recipients to their responsibilities regarding these protections.

## Biospecimen Collection and Management

Describe the system for collecting, storing and distributing biospecimens.

Confidentiality. How will you ensure the confidentiality of the specimens, from collection through use? Describe the Code/ID number assignment and the maintenance of the linkage (if any) between the specimen and the subject’s PHI. Specimens that are linked to a Master List are “coded” or “linked”. Specimens that cannot be linked back to the donor because no PHI is ever attached are “anonymous”. Specimens that have the linkage removed are said to be “deidentified” or “anonymized”. Rarely are specimens deidentified; they are almost always coded.

Storage. Where will the specimens be stored? If samples are going to more than one location, list each location. How will the specimens be tracked? Describe the storage facilities and equipment.

Security. Describe plans for controlling access to specimens and limiting use to the purposes outlined in the consent document.

## Sharing Data and Specimens with Future Investigators

The Registry/Repository should be designed and planned to maximize the use of the collected data/specimens with a minimum of regulatory oversight. Without careful planning, the future use of data/biospecimens by recipient investigators can be subject to IRB oversight. The Policies and Procedures (SOPs) for the Registry/Repository can minimize the obstacles for future use, the need for IRB review and approval, and will maximize the usefulness of the materials collected.

If data/biospecimens will be provided to investigators without any elements of PHI and the Registry/Repository has a clear policy prohibiting release of identifiers, then the future use of data/biospecimens will not require IRB oversight for recipient investigators.

If the data/biospecimens will be provided to investigators with a limited dataset (dates and/or city, state and zip code), then the procedures for obtaining a data use agreement between the Registry/Repository (the provider) and the recipient investigator should be described.

For more information about data sharing, see the IRB website pages on [Sharing Data](https://irb.research.chop.edu/sharing-data). The information on this page explains when data/specimens can be shared (1) without any regulatory oversight, (2) when a data use agreement is needed, (3) when the research requires a determination of exemption from the IRB and (4) when it requires IRB approval.

## Providing Results to Subjects

Describe the plans, if any, for reporting research results to subjects and results of any incidental findings that are clinically significant. The plan needs to be detailed and robust. Who will provide the counseling when offering subjects the option to receive or not receive results? Who will meet with the family and provide the results? What are their qualifications for discussing the implications of the findings? What are the plans to communicate results to others (e.g., family physician)?

Only tests that have clinical significance can be reported back to families. Clinical significance means that the test results have (1) analytic validity (e.g. FDA-approved tests, consensus on validity, performed in a CLIA-certified lab) and (2) known clinical utility, meaning there are important implications to the participant's health and well-being and there are effective preventive measures, treatments or interventions currently available. See the IRB’s [Return of Results consent form addendum](https://irb.research.chop.edu/consent-templates) for additional guidance.

**NOTE**: CMS prohibits returning test results not performed in a CLIA-certified lab to subjects. See the IRB website page on [Incidental Findings](https://irb.research.chop.edu/incidental-findings) for more information.

## Regulatory and Ethical Considerations

### Risk Assessment

Summarize all anticipated risks from the study. All studies have at least some risk, even if it is no greater than minimal. For example, in chart reviews, the primary risks are breach of privacy and confidentiality. Sometimes, for example with genetic research, the risks include harms to groups other than just the subjects themselves, such as stigmatization and insurability.

Risks should be expressed in terms of magnitude and probability of harm. Address how the study design and execution will minimize the risks of harm.

### Potential Benefits of Participation

Summarize all potential benefits, if any, from participation. Benefits should be broken down into direct benefits (accrue to the study subject as a result of participation - unlikely in a repository/registry) and indirect benefits (benefits that accrue to the individual or society in the future). Registry/Repositories are set up to foster future research and therefore direct benefit is almost never applicable.

### Risk-Benefit Assessment

The Risk-Benefit assessment should include justification for proceeding with the study based on the balance between risks and benefits

## Recruitment Strategy

For a purely retrospective study, describe the case ascertainment procedures to identify eligible subjects (records).

Describe the approach to recruiting subjects. Where will they come from? How will the investigator identify prospective subjects? Will the subjects come from the investigator’s patients or will they be patients of other care providers? If the prospective subjects are not patients of the investigator, who will first approach the subjects and by what method (in person, via mail, via telephone contact)? Will advertising be used (**NOTE:** All recruitment materials that subjects will see and/or hear must be reviewed and approved by the IRB before they are used to recruit subjects)? Will there be sufficient subjects to achieve the study goals?

If eligibility screening requires collection of data about prospective subjects (via medical record review, direct query or other procedures), and this screening will take place before subjects consent to participation in the main study, describe the plan for obtaining consent/assent and HIPAA authorization for the screening (unless the screening either qualifies for waivers of consent/assent/HIPAA authorization or does not require prior informed consent/assent/HIPAA authorization [see Sections 4.1 & 6.8.1 for additional information]).

For more information, see the IRB’s webpage on the differences between [Recruitment vs Screening](https://irb.research.chop.edu/recruitment-vs-screening).

## Informed Consent/Assent and HIPAA Authorization

Describe the procedures that will be used to obtain informed consent/HIPAA Authorization and assent. Include: who will obtain consent and assent, where will consent/assent process take place, how privacy will be assured (e.g. the consent conference will occur in a private exam room), how much time will subjects be permitted to make a decision, how the investigators will assure that subjects comprehend the nature of the study, the study procedures and the risks and benefits of participation, steps that will be taken to avoid coercion and documentation of consent. Also, include whether a stand-alone HIPAA Authorization will be used or a combined consent-authorization document.

**NOTE:** Written consent and HIPAA authorization are required for the collection of samples in a Repository.

If the study includes several populations or scenarios for obtaining consent, create subsections to address them (e.g. for those who provide consent/assent/HIPAA authorization in person, those who provide consent/assent/HIPAA authorization over the phone, etc.).

### Screening

Describe the process for screening procedures, including location (e.g. in person, over the phone, etc.). If no screening procedures will be conducted, delete this sub-section.

The IRB may approve screening procedures without obtaining the prior informed consent of the prospective subject or the subject’s legally authorized representative only if the solicited information is limited to the minimum necessary for screening/determining eligibility for the main study AND if these procedures are limited to: (a) obtaining information through oral or written communication with the prospective subject or legally authorized representative, or (b) obtaining identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens. NOTE: If the information or biospecimens used for the purpose of screening, recruiting, or determining the eligibility of subjects include protected health information (PHI), HIPAA applies and HIPAA Authorization may still need to be obtained prior to conducting these screening activities. See the IRB’s webpage on [Recruitment vs Screening](https://irb.research.chop.edu/recruitment-vs-screening) for more information.

### Main Study

#### Existing Specimens (those collected between MM/DD/YYYY and MM/DD/YYYY)

A waiver of consent and assent is being requested per 45 CFR 46.116(f)(3)/45 CFR 46.408 and a waiver of HIPAA authorization is being requested per 45 CFR 164.512(i)(2)(ii). As the investigator will need to link subject data from multiple sources, the research could not be practicably carried our without using data in an identifiable format.

Subjects were seen over the last XXX years, many have moved out of the area and/or up-to-date contact information is not available, making it impracticable to conduct the research without the waivers. In addition, due to a rarity of the condition, the investigators need to enroll all eligible subjects to ensure scientific validity.

*If applicable*: As part of study XXX (IRB #XXX), subjects agreed to the future use of their samples/data.

#### Prospectively Collected Specimens

Describe the consent process for main study procedures, including location (e.g. in person, over the phone, etc.) and consent/assent/HIPAA authorization determination requests (e.g. written consent/assent/HIPAA authorization will be obtained on paper or via REDCap).

#### Decedents

If decedents’s samples and identifiable data will be included in the repository, add the following (if not, delete this sub-section):

A waiver of HIPAA authorization per 45 CFR 164.512(i)(1)(iii) is requested for the review of medical records of decedents. Decedents are no longer human subjects (a waiver of consent is therefore not required). Not including these decedents, however, would make it impossible to avoid selection bias. It would thus be impracticable to conduct the research without the waiver of HIPAA authorization.

#### Fetal Material

If decedents’s samples and identifiable data will be included in the repository, address the following (if not, delete this sub-section): How the investigators will ensure that all fetal material has been/will be collected in accordance with federal regulations and the PA Statute (Title 18 – Crimes and Offenses, Chapter 32 Abortion; § 3216. Fetal experimentation).

### Consent/HIPAA Authorization Plan for Subjects Who Reach Age of Majority

Describe the consent/HIPAA authorization process for individuals who become legal adults while enrolled in the study. If subjects will provide verbal consent/HIPAA authorization for their continued participation (e.g. if they are contacted over the phone), make sure all study materials request a waiver of documentation of consent and alteration of HIPAA (to obtain verbal authorization), and that a verbal consent/HIPAA authorization form is provided. If no subjects will reach the age of majority while enrolled, delete this section.

### Individuals with Limited English Proficiency

Describe the consent/assent/HIPAA authorization process for individuals with limited English proficiency. If subjects will be enrolled over the phone, also outline the role of the interpreter in the phone conversation (i.e. will they be physically present with the investigator or conferenced into the call, how will interpreters/witnesses document their role in the consent process, etc.).

### Annual Confirmation of Continued Willingness to Participate

If the repository continues to collect specimens over several years (e.g. at each annual visit or at each clinical endoscopy), describe the process to assess subejcts’ continued willingness to participate (at least annually). This does not have to be a formal re-consent, but could be a conversation to confirm continued willingness to participate that is documented in the study chart.

## Payment to Subjects/Families

If subjects or parents/guardians are to be paid for the inconvenience of participating in the study, the amount of payment(s) must be stated in the protocol. The amount paid to parent/guardians should be separated from the amount paid to subjects. The IRB must review both the amount and method of payment to subjects to insure that neither presents an undue influence on the trial subjects. Subjects not completing the study, for whatever reason, must be paid on a pro rata basis.

## Confidentiality

Include a statement that all data and records generated during this study will be kept confidential in accordance with Institutional policies and HIPAA on subject privacy and that the Investigator and other site personnel will not use such data and records for any purpose other than conducting the study. Describe the safeguards to maintain subject confidentiality (you may say, “Safeguards are described under Data Collection and Management,” if no additional detail is required. An important point: If the investigator leaves the institution and takes the data, or shares the data with an outside colleague (even one at UPenn), additional HIPAA requirements must be satisfied.

# SAFETY MANAGEMENT

The template language below assumes that the Registry/Repository is a minimal risk study. If the risks of study procedures are greater than minimal, consult the Intervention Protocol Template for Safety Management language.

## Clinical Adverse Events

Unanticipated problems involving risks to subjects and others will be monitored throughout the study.

## Adverse Event Reporting

Since the study procedures are not greater than minimal risk and are limited to existing data and specimens, SAEs are not expected. If any unanticipated problems related to the research involving risks to subjects or others happen during the course of this study these will be reported to the IRB in accordance with CHOP IRB SOP 408: Unanticipated Problems Involving Risks to Subjects. AEs that do not meet prompt reporting requirements will be summarized in narrative or other format and submitted to the IRB at the time of continuing review (if continuing reviews are required), or will be tracked and documented internally by the study team but not submitted to the IRB (if continuing reviews are not required).

# PUBLICATION

Describe the plans for publication and confirm that only aggregate data without individually identifiable information will be published. ***Note that the inclusion of illustrative cases in such reports may result in disclosure of identifiable information****.* Consider this eventuality. If the CHOP investigator will not have access to the complete data set, or if this is multicenter study, describe how publication will proceed.

# References

Appendix

Attach a listing of data elements from each data source, if not listed in Sections 4 and 5.

Attach a listing of any questionnaires or surveys that are not included in the IRB's listing of [Validated Instruments](https://irb.research.chop.edu/validated-instruments), if not attached in eIRB Section 12.02 (2.0).