PROTOCOL TEMPLATE: DESCRIPTIVE STUDY

The protocol template is a tool to help facilitate the development of protocols for retrospective chart reviews. This includes chart reviews of existing data that have purely descriptive objectives approvable under Expedited Category 5. See the CHR website for more information about Expedited Review Categories. http://www.research.ucsf.edu/chr/Guide/chrExRevCat.asp

The template contains some sample text and/or instructions for what type of information to include in the protocol.

- Criteria to meet retrospective status (Exempt/Expedited) for review:
  - Protocol must be research involving materials (data, documents, records or specimens) that have been collected solely for the non-research purposes (such as medical treatment or diagnosis).
  - Protocol must include specific dates of data/information etc. that will be used.
  - All data must be in existence at the time of IRB submission.

  **Note: If all data are recorded in a de-identified manner, then the study would be exempt. However, if a link to other sources needs to be recorded with the data, then the study would be expedited and waiver of consent and HIPAA would be required.*

- It is recommended that primary section headings in the template be retained to facilitate the review process. If not appropriate for a given protocol, insert "Not Applicable" after the section heading. Delete unneeded text and/or sub-headings.

- Protocol Template instructions and sample text are in *italics*. As you complete information requested in the template, please replace or delete the italicized text and/or instructions and this first page of instructions prior to submission for review.

- *Sample text* may be modified as necessary or appropriate to meet the scientific aims of the protocol. Reformat *italicized sample text* to regular text.

- NOTE: The investigator must demonstrate that the study is consistent with "sound scientific design" and that the design is sufficient to achieve the study objectives. The investigational plan, study procedures, and analysis plan must provide sufficient details to provide the CHR with a basis for its decisions. Even though the risks of the research may be minimal, the CHR will not approve studies that provide insufficient information.

Be sure to update the Table of Contents after the protocol is finalized. In MS Word, select to highlight the table, then update using the REFERENCES tab, ***Update Table****.*

RETROSPECTIVE CHART REVIEW PROTOCOL TITLE

Principal Investigator:
(List PI's name, degree, position, affiliation, address, telephone, e-mail)

Co-Investigators:
(List PI's name, degree, position, affiliation, address, telephone, e-mail)

Research Personnel:
(List PI's name, degree, position, affiliation, address, telephone, e-mail)

Study Site(s): *(List all sites involved)*

Protocol Version: *(1.0)*

Protocol Date*: (month/day/year)*

TABLE OF CONTENTS

ABBREVIATIONS AND DEFINITIONS OF TERMS

	Insert and delete terms as relevant
°C	Degrees centigrade
AE	Adverse event

ABSTRACT

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 or study question
- If more than 1 objective, limit to only the key secondary objectives.

Study Design:

- Basic design: Retrospective (cohort, case-control or descriptive) study

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

Study Interventions and Measures:

- Review of medical records
- Main study outcome measures (assessments of primary and key secondary endpoints)

1 BACKGROUND INFORMATION AND RATIONALE

The background and rationale should be approximately 3 – 5 pages.

1.1 Introduction

Brief paragraph or two to describe the setting and rationale for the study. The details of the background go into Section 1.2

1.2 Relevant Literature and Data

Overview of the literature and data relevant to the trial and provide background for the trial. Also the relevant literature establishing the validity for scales, evaluation tools etc. The reference citations should be listed at the end. It is usual to limit this to 10 (at most 20) key references.

1.3 Compliance Statement

This study will be conducted in full accordance all applicable UCSF 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 UCSF Committee on Human Research 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.

2 STUDY OBJECTIVES

State the objectives of the study.

The purpose of the study is to determine the (outcomes, prevalence, complications) of ….

2.1 Primary Objective (or Aim)

The primary objective of this study is to determine the whether the XXX (presenting sign, comorbidity, treatment option) reduces, increases, etc. outcome measure XXX in children X to X years. This should be specific, for example: “to determine whether children less than 3 years of age are at higher risk of post-tonsillectomy airway complications than older children.”

2.2 Secondary Objectives (or Aim)

The secondary objectives are to: For example, “describe the indications for tonsillectomy as a function of age.”

- For example, “describe the indications for tonsillectomy as a function of age.”
- Etc.

3 INVESTIGATIONAL PLAN

3.1 General Schema of Study Design

Section 3.1 is intended to be a brief overview. Do not put the details of the entire study into this Section. Section 4 is where the details of the study and its procedures belong.

This study is a retrospective (cohort study, descriptive study, case-control study, etc.) .

3.2 Study Duration, Enrollment and Number of Sites

3.2.1 Date Range of Study

The range of dates during which the study will take place and will be included in the research. For example, "Cases will be included if the initial surgery was between 1/1/1995 and 12/31/2005. Follow-up information though 6/1/2006 will be included, as well as history preceding the initial surgery." If the study has a prospective component, the Observational Study Protocol Template should be used.

3.2.2 Total Number of Study Sites/Total Number of Subjects Projected

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

Recruitment will stop when approximately XXX subjects are ….. It is expected that approximately XXX subjects will be enrolled (identified for further review) to produce XXXX evaluable subjects.

Every record reviewed to ascertain whether the subject is eligible is "enrolled" and every one that meets all of the enrollment criteria and has the necessary data to be included in the analysis is "evaluable". Usually many more charts will need to be reviewed than the number of evaluable subjects required.

3.3 Study Population

Even though the study is retrospective, there is a need to define the study population using inclusion and exclusion criteria. These are the criteria that will be used to determine whether or not to include a prospective subject in the study.

3.3.1 Inclusion Criteria **(examples)**

1) Males or females age 0 to 16 years.

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).

3.3.2 Exclusion Criteria (examples)

1) Previous tonsillectomy, here or elsewhere

2) Named craniofacial syndrome

4 STUDY PROCEDURES

The study procedures are limited to review of existing medical records and use of existing biological specimens (if applicable).

4.1 Data Sources

4.1.1 Case ascertainment

Describe how the potential cases and controls (if applicable) will be identified. How will the investigator determine that the prospective subjects meet the enrollment criteria?

For example, "Potential cases will be identified by querying billing records for surgeries with the procedure code NNNNN. IDX will be checked to identify cases in the appropriate age range, who were scheduled for 23-hour admissions. The data sheet (see appendix) contains a box with inclusion criteria, which the chart abstractor will verify before continuing with the abstraction. ."

4.1.2 Data sources

This description should be specific but not over-detailed. It is important to explain that the data truly are available from non-research sources. For example, "EPIC will be queried for demographic information, admission dates and discharge diagnoses. Surgical information will be abstracted from the Operative Note. Tissue diagnosis will be obtained from Pathology Records."

If data are from research sources, for example for reanalysis of existing research data, provide the original CHR number and quote the section of the consent form that allows this use.

4.2 Data Elements to Abstracted

Provide a listing of all of the variables that will be abstracted from the medical records by source of the data.

4.2.1 APeX

- Date of birth
- Date of admission
- Weight
- Height

- Admission diagnosis
- Etc.
- Date of surgery
- Anesthetic agents
- Pain medications
- Intra-operative complications
- Etc.

4.2.2 Pathology

- Tumor specimen
- Etc.

5 STATISTICAL CONSIDERATIONS

This section should describe soundness of scientific design, even in minimal-risk matters as chart reviews. Also, it is to the investigator's advantage to plan the analysis in advance, insuring that data are coded in such a way that they can readily be analyzed and that sample size will be appropriate.

5.1 Primary and Secondary Endpoints

The endpoints refer directly to the objectives and are the specific expression of what will be measured and/or compared in the study. Example: "The primary **objective** is to determine whether tonsillectomy increases weight gain. The primary **endpoint** will be the difference in weight 2 months after surgery compared to the 2 months before surgery.

5.2 Measures to Avoid Bias

Briefly describe the measures to be taken to avoid bias (details can be given in the Study Procedures section). For example, radiographic studies might be read by a radiologist who is blind to the diagnosis. Cases might be include only if the initial presentation was within the study window; otherwise complex cases or recurrent disease might be over-represented in the sample because both old and new cases would be captured.

5.3 Statistical Methods

The statistical methods refer should address each endpoint. Adjustments for confounding variables and ascertainment of evidence of biases should be addressed. If the study is purely descriptive then just state the data will be summarized using descriptive measures.

Example: "Baseline and demographic characteristics will be summarized by standard descriptive summaries (e.g. means and standard deviations for continuous variables such as age and percentages for categorical variables such as gender)."

Example: "The primary objective is to determine whether there is an association between age and risk of airway complications. Because 'complication' is a dichotomous variable, a point-biserial correlation will be calculated."

Example: "The paired t-test will be used to compare differences in weight gain for the 2 months prior to surgery and the 2 months after surgery.

5.4 Sample Size and Power

The sample size should be justified based on the study objectives and should be determined as for any other study.

Even if the number of cases available is limited, an estimate should be made in advance, perhaps by obtaining an aggregate report of the number admissions with the diagnosis of interest. Even if there are too many uncertainties to calculate power precisely, an estimate can be made, based on clinical experience. If sample size is limited, determine the effect size that you can reasonable expect to detect. For some descriptive studies, the sample size will be one of convenience – all of the available cases. If that is the case, then simply state that it is a convenience sample.

6 STUDY ADMINISTRATION

6.1 Data Collection and Management

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

1. Confidentiality of Data. How will you ensure the confidentiality of the data, from the beginning of the abstraction process though analysis? For paper records, one way is to keep a master list separate from data forms that have only a study number. Another is to use password-protected files; in Excel, type "password" in the Help box for instructions. NOTE: if any of the investigators who access identifiable data are not in the UCSF workforce, there are important HIPAA rules on disclosure.

2. Security. Have a plan for backing up or otherwise recovering data.

3. Anonymization, de-identification or destruction. Have a specific plan, for example, "The identifiers will be destroyed after publication. The other data will be retained for three years. This laboratory maintains a file drawer specifically for such archives, each folder labeled "Destroy by…," with the earliest dates at the front."

6.2 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, additional HIPAA requirements must be satisfied.

6.3 Regulatory and Ethical Considerations

6.3.1 Risk Assessment

All studies have at least some risk, even if it is not greater than minimal. For chart reviews the primary risk is that of breach of confidentiality of data. Sometimes, for example with genetic research, the risks include harms to groups other than just the subjects such as stigmatization and insurability.

Address how the study design and data protection plan will minimize the risks of harm.

6.3.2 Potential Benefits of Study Participation

Summarize all potential benefits, if any from study participation. Benefits should be broken down into direct benefits (accrue to the study subject as a result of participation; unlikely for retrospective studies) and indirect benefits (benefits that accrue to the individual or society in the future).

6.3.3 Risk-Benefit Assessment

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

6.4 Informed Consent/Assent and HIPAA Authorization

Either informed consent must be obtained or the investigator must request a waiver of informed consent, a waiver of assent (when children are subjects) and a waiver of HIPAA Authorization.

When Consent will be obtained, describe the procedures that will be used to obtain informed consent. Include: who will obtain consent, where will consent process take place, how will privacy be assured, how much time will subjects be permitted, how will the investigators assure that subjects comprehend the nature of the study, the study procedures and the risks-benefits of participation, steps that will be taken to avoid coercion and documentation of consent.

If consent will be obtained, describe the process for obtaining informed consent and child assent. Who will approach the family/subject? When and where will this occur?

6.4.1 Waiver of Consent

If the study appears to qualify for waiver of consent (studies limited to existing data), the protocol must provide sufficient information explaining why the research meets the criteria of 45 CFR 46.116(d) so that the CHR can grant the request. The iRIS application will request this same information.

> **45 CFR 46.116(d)** An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth in this section, or waive the requirements to obtain informed consent provided the IRB finds and documents that:
>
> (1) the research involves no more than minimal risk to the subjects;
>
> (2) the waiver or alteration will not adversely affect the rights and welfare of the subjects;
>
> (3) the research could not practicably be carried out without the waiver or alteration; and
>
> (4) whenever appropriate, the subjects will be provided with additional pertinent information after participation.

6.4.2 Waiver of Assent

Even when the IRB waives parental permission, it must still waive assent. The criteria of §116(d) listed above must be met to obtain a waiver of assent.

Assent could also be waived (with or without a waiver of parental permission) under 45 CFR 46.408, if the capability of some or all of the children is so limited that they cannot reasonably be consulted.

In either case, the request to waive assent must be justified and appropriate for the study being proposed.

6.4.3 Waiver of HIPAA Authorization

The criteria for waiver of HIPAA Authorization are similar to, but different than those for waiver of consent.

45 CFR 164.512(i.)(2)(ii) A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

(A) The use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:

(1) an adequate plan to protect the identifiers from improper use and disclosure;

(2) an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and

(3) adequate written assurances that the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;

(B) The research could not practicably be conducted without the waiver or alteration; and

(C) The research could not practicably be conducted without access to and use of the protected health information.

See the CHR website for more information about Waivers of Consent, Assent and HIPAA. http://www.research.ucsf.edu/chr/Recruit/chrRC.asp

7 PUBLICATION

Describe any plans for publication and presentation. ***Note that the inclusion of illustrative cases in such reports may result in disclosure of identifiable information***. Consider this eventuality.

8 REFERENCES

APPENDIX

Append relevant information.