

Research Proposal for Descriptive Studies

Title: The complete title of the protocol

Short Title myIRB will request a short title of up to 5 words for tracking purposes

Funding Information:

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Amendment 1 Date: None

Amendment 4 Date: None

Amendment 2 Date: None

Amendment 5 Date: None

Amendment 3 Date: None

Amendment 6 Date: None

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The highlighted text is instructional and should be deleted before finalizing the document and submitting it to the IRB.

This simplified protocol template may be used for descriptive research that does not qualify for the exemption (see the IRB's Exempt FAQ page at <http://irb.ufl.edu/irb02/forms-templates-guidelines/irbrev.html> and <http://irb.ufl.edu/myirb/myirb-help-selecting-the-requested-review-type.html>), when the research has purely descriptive objectives approvable under Expedited Category 5 (please note that there is no website which lists these categories. This information is only presented in myIRB). All other observational studies should use the Observational Study Protocol Template. See the IRB website for more information about Expedited Review (<http://irb.ufl.edu/myirb/myirb-help-selecting-the-requested-review-type.html>).

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 IRB with a basis for its

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decisions. Even though the risks of the research may be minimal, the IRB will not approve studies that offer insufficient information.

Sections that are not applicable can be marked “not applicable.” Delete all of “Instructional text” when the protocol is complete and before submission to the IRB.

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ABBREVIATIONS AND DEFINITIONS OF TERMS

Abbreviation	Description
°C	Degrees centigrade
AE	Adverse event

ABSTRACT

Start here. See instructions below.

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 or study question
- If more than one objective, limit to only the key secondary objectives.
- Study Design:
 - Basic design: Retrospective/Prospective (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 Measures:
 - Review of records or use of leftover biological specimens (identifiers are recorded)
 - Main study outcome measures (assessments of primary and key secondary endpoints)

1 BACKGROUND INFORMATION AND RATIONALE

The background and rationale should be no more than 3 – 5 pages.

1.1 Introduction

A 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 in Section 11. 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 with all applicable University of Florida 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 non-compliance will be documented.

The investigators will perform the study in accordance with this protocol, will obtain consent/assent/HIPAA authorization (unless waivers are granted), and will report unexpected problems in accordance with The University of Florida 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.

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 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.”

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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.”
- Additional secondary objectives as applicable

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 (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 IRB needs to 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 after X/X/XX.”

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 everyone 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

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 X – X years at the time of surgery.
- 2) Tonsillectomy (with or without adenoidectomy) after X/X/XX.
- 3) Completed operative note
- 4) Additional criteria as required
- 5) Parental/guardian permission (informed consent) and, if appropriate, child assent. (Include ONLY if a waiver of informed consent is not appropriate).

3.3.2 Exclusion Criteria (examples)

- 1) Previous tonsillectomy, here or elsewhere
- 2) Named craniofacial syndrome
- 3) Additional criteria as required

4 STUDY PROCEDURES

The study procedures are limited to review of records and use of leftover biological specimens (if applicable). For example, if specimens were collected for clinical purposes or for another research study, and will undergo further analysis as part of this study.

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. EPIC IT will be checked to identify cases in the appropriate age range, who were scheduled for 23-hour admissions. The datasheet (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 for the Committee to be able to see 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 research data, provide the original myIRB number and quote the section of the consent form (if applicable) that allows this use.

4.2 Data Elements to Abstracted (examples)

Provide a listing of all of the variables that will be requested from the EPIC IT Team or another source of the data.

4.2.1 Data Elements (including the IDC codes):

- Name of treating physician
- Parental income
- Date of birth
- Date of admission
- Admission diagnosis
- Additional data points as applicable

4.2.2 Data Source 2

- Data points as applicable

4.2.3 Data Source 3 (e.g., Pathology)

- Tumor specimen
- Data points/specimens as applicable

5 STATISTICAL CONSIDERATIONS

The IRB is required to consider the soundness of scientific design, even in such minimal-risk matters as chart reviews. Also, it is to the investigator's advantage to plan the analysis in advance, ensuring 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 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 two months after surgery compared to the two months before surgery.

5.2 Measures to Avoid Bias

Briefly describe the measures to be taken to avoid bias (details can be given in Section 4). For example, radiographic studies might be read by a radiologist who is blind to the diagnosis. Cases might be included 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 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 two months before surgery and then two 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 of 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 the sample size is limited, determine the effect size that you can reasonably 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 through 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 UF-JAX workforce, there are important HIPAA rules on disclosure.
2. Security. Have a plan for backing up or recovering data. This can be as simple as a copy of the password-protected file on one of the secure servers provided by the Office of Research (ORA) or REDCap database, etc.
3. Anonymization, de-identification, or destruction. Have a specific plan, for example, “The identifiers and other data will be destroyed six years after study completion, in compliance with UF’s Data Retention Policy. 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 (even one at Penn), additional HIPAA and institutional requirements must be satisfied.

6.3 Regulatory and Ethical Considerations

6.3.1 Risk Assessment

Risks are either not greater than minimal, a minor increase above minimal or greater than minimal. Describe the risks of each research procedure in terms of magnitude and probability of harm. Consider all physical, psychological, economic, or societal harms that might accrue to subjects or others.

Distinguish between risks associated with routine clinical care from those that will occur as a result of research. Summarize the overall anticipated risks from the study intervention and study-related procedures.

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 harm to groups other than just 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 these types of 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 is 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 is 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 a waiver of consent, the protocol must provide sufficient information explaining why the research meets the criteria of 45 CFR 46.116(f)(3) so that the IRB can grant the request. The myIRB application will request this same information.

45 CFR 46.116(f)(3) 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;
- (4) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; and
- (5) 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(f)(3) 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 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 the 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

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(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 IRB website for more information about <http://irb.ufl.edu/index/irb-policies-guidelines-and-guidances.html>.

6.5 Payment to Subjects/Families (delete if not applicable)

Ordinarily, this is not applicable for descriptive studies. However, if payment to subjects/families is involved in some way, consider the following: The IRB must review both the amount and method of payment to subjects to ensure 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.

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. Reimbursement for travel, meal, and parking expenses should be presented separately from payments for the time, effort, and inconvenience. The amount paid to parents/guardians should be separated from the amount paid to subjects. A wage model is the preferred model to use as the basis for payments. For children, this is based on the types of jobs that children can typically attain, such as babysitting, raking leaves, etc. See <http://irb.ufl.edu/index/irb-policies-guidelines-and-guidances.html>.

6.5.1 Reimbursement for travel, parking, and meals

Amount per visit, justification, and form of reimbursement.

6.5.2 Payments to parent for time and inconvenience

Amount per visit, justification, and form of payment.

6.5.3 Payments to the subject for time, effort and inconvenience

Amount per visit, justification, and form of payment.

6.5.4 Gifts

If any tokens of appreciation will be given to subjects or families, these should be described here.

7 SAFETY MANAGEMENT

The UF-JAX PI will monitor and review the study progress, subject safety (if applicable), and the accuracy and security of the emerging data.

7.1 Clinical Adverse Events

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

7.2 Adverse Event Reporting

Since the study procedures are not greater than minimal risk, 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 (including SAEs) these will be reported to the IRB in accordance with UF IRB (see: <http://irb.ufl.edu/index/irb-policies-guidelines-and-guidances.html>). AEs that do not meet prompt reporting requirements should 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).

8 PUBLICATION

Describe the plans for publication and presentation. *Note that the inclusion of illustrative cases in such reports may result in the disclosure of identifiable information.* Consider this eventuality. If the UF-JAX investigator will not have access to the complete data set, or if this is a multicenter study, describe how the publication will proceed.

9 REFERENCES

All references belong in this section.

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APPENDIX

Append relevant information. Delete if not applicable.